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Supreme Court, U.S.
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(1)
07-770 DEC 6 - 2007
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No. 07-

IN THE

Supreme Court of the United States

UNITED STATES *ex rel.* MICHAEL FOWLER, PEPPI FOWLER, VICTOR CORTES, and DANNY NEVAREZ,

Petitioners,

v.

CAREMARK RX, L.L.C., and CAREMARK INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. In their Third Amended Complaint ("TAC"), the Petitioners asserted claims pursuant to 31 U.S.C. §§ 3729 (a)(1),(a)(2) and (a)(7) of the False Claims Act ("FCA"), alleging that the Defendants knowingly submitted false claims for payment to the United States. The Seventh Circuit upheld dismissal of the Relators' claims by adding additional pleading elements to Sections (a)(1) and (a)(2) of the FCA. Specifically, the Seventh Circuit held that to satisfy Fed. R. Civ. P. 9(b), a Relator must *affirmatively prove* (at the pleading stage no less) that the defendant *did not* repay, credit, or otherwise make the government whole at some point in the future, *after* the defendant initially submitted, or caused to be submitted, a false claim for payment. This holding is in conflict with the text and purpose of the FCA, with decisions from other Circuits that have held that liability under the FCA attaches once a false claim is submitted, and is contrary to sound public policy. Thus, the first question presented is whether, under the FCA, a defendant can avoid liability from its submission to the United States of a false claim because it could, in theory, repay the government at some point in the future, the money it initially wrongfully obtained.

2. In the TAC, the Petitioners alleged that the Defendants knowingly submitted specifically identified false claims, in addition to alleging substantial facts from which that knowledge could also be inferred. The District Court found that the TAC did not satisfy Fed. R. Civ. P. 9(b)'s ("Rule 9(b)") requirement that "[i]n all averments of fraud . . . , the circumstances constituting fraud . . . shall be stated with particularity." Specifically, the

District Court held *inter alia*, that although the Petitioners identified specific false claims, they were required to prove, at the pleading stage, that the defendant had engaged in a "pattern and practice" of submitting false claims. The Seventh Circuit upheld that result, but for different reasons. Specifically, the Seventh Circuit held that the Petitioners were required to plead with particularity, *and prove* at the pleading stage, that the false claims submitted by the Defendants were "knowingly" submitted. The Seventh Circuit explained that this heightened pleading standard was necessary in situations where the submission of a false claim arises from a defendant's violation of contractual provisions, reasoning that anything less creates strict liability for mere breaches of contract. Accordingly, the additional questions presented are: (a) what level of specificity satisfies Rule 9(b); and (b) pursuant to Rule 9(b), in situations where a false claim arises from a violation of contractual terms, is a relator required to provide, at the pleading stage, admissible evidence of "knowledge" or may such state of mind be averred generally?

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Petitioners Michael Fowler, Peppi Fowler, Victor Cortes and Danny Nevarez, ("Whistleblowers" or "Relators"), respectfully submit this Petition for a Writ of *Certiorari* to review the judgment of the United States Court of Appeals for the Seventh Circuit.

OPINIONS BELOW

The Seventh Circuit's Opinion is reported at 496 F.3d 730. Petitioners' Appendix ("Pet. App.") A. The Seventh Circuit's Order denying the Petition for Rehearing with Suggestion for Rehearing *En Banc* is unreported. *See* Pet. App. C. The Opinion of the United States District Court for the Northern District of Illinois from which the appeal was taken is unpublished, but is electronically reported at 2006 WL 3469537. *See* Pet. App. B.

JURISDICTION

The District Court had jurisdiction over Petitioners' claims pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Seventh Circuit had jurisdiction to review the District Court's final judgment pursuant to 28 U.S.C. § 1291. The Seventh Circuit filed its Opinion on July 27, 2007. It denied the Petitioners' timely filed Petition for Rehearing with Suggestion for Rehearing *En Banc* on Sept. 7, 2007. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION AND RULE INVOLVED

I. Title 31 U.S.C. § 3729, which provides, in relevant part:

§ 3729. False claims

(a) Liability for certain acts.

Any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> * * *
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

II. Federal Rule of Civil Procedure 9(b) which provides:

Fraud, Mistake, Condition of the Mind.

> In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.

STATEMENT OF THE CASE

I. Introduction

This Court has long recognized the importance of the FCA and has in fact recently addressed several hotly contested issues arising under the FCA in the lower courts. *See Rockwell Int'l Corp. v. United States*, 549 U.S. __, 127 S. Ct. 1397 (2007) (addressing subject matter jurisdiction and the "original source exception to the FCA's "public disclosure" jurisdictional bar); *Allison Engine Co., Inc. v. United States ex rel. Sanders*, No. 07-214 (Oct. 29, 2007) (addressing whether a claim must have been "presented" to the United States to be actionable under the FCA). However, unlike the more narrow issues raised in *Rockwell* and *Sanders*, the issues raised in this case affect nearly every case brought under to the FCA.

Accordingly, not only does this case afford the Court with the opportunity to interpret specific provisions of the FCA, but it also gives this Court an opportunity, for the first time with respect to an FCA case, to provide the lower courts with long needed guidance regarding

the biggest hurdle facing whistleblowers — Fed. R. Civ. P. 9(b) — a Rule that has been applied so inconsistently in the lower courts that successfully satisfying Rule 9(b) has become, at best, so unpredictable that whether a Relator's claims can survive a motion to dismiss on Rule 9(b) grounds is now almost solely dependent upon the "luck of the draw" as to what judge happens to be assigned to a given case, and at worst, in some Circuits has become nearly impossible.

A. Caremark's Fraudulent Schemes

The Whistleblowers brought this action on behalf of the United States of America ("United States") as Relators under the FCA against Respondents Caremark Inc. and Caremark Rx, Inc. (collectively, "Caremark"). Caremark, one of the country's largest pharmaceutical benefits managers ("PBMs"), entered into a series of contracts (the "Federal Contracts" or "Contracts") with the United States through various health plans ("Federal Plans") available to Federal employees and retirees, and their dependents ("Federal Plan Members"). Through those Contracts, Caremark agreed to provide to Federal Plan Members mail-order prescription drugs through four large mail order pharmacies and from more than twenty specialty pharmacies located throughout the country. Caremark also agreed to provide various clinical services purportedly aimed at improving the level of care received by Federal Plan Members and also purportedly aimed at saving the Federal Plans money by changing the drug usage of Federal Plan members to purportedly lower cost alternatives. In exchange, the United States, through the Federal Plans, paid Caremark several billion dollars.

The Whistleblowers, all former employees of Caremark who possessed first-hand and intimate knowledge of Caremark's fraudulent activities, alleged that Caremark engaged in numerous fraudulent billing schemes that resulted in the submission by Caremark to the United States of numerous false claims for payment. The Seventh Circuit chose to only substantively address two of those schemes, which are described below.[1]

1. Caremark's Returned Drugs Scheme

In their TAC, the Whistleblowers alleged that Caremark improperly billed the United States in situations where Federal Plan members, or others on their behalf, returned prescription drugs to Caremark for a variety of reasons. With respect to most of those returned drugs, Caremark knew, at the time that it submitted claims for payment to the United States, that the drugs had already been returned.[2] The

1. With respect to the other four schemes alleged by the Whistleblowers in their TAC, the Seventh Circuit completely ignored one of them. With respect to the other three, the Seventh Circuit held that the Whistleblowers did not devote enough of their brief addressing these schemes and declared them waived. *United States ex rel. Fowler v. Caremark Rx, L.L.C.*, 496 F.3d 730, 743 (7th Cir. 2007) ("*Fowler*"); Pet.App.A at 24a-25a. Although, the Whistleblowers vigorously dispute that holding, it is immaterial for the purposes of this Petition because the Seventh Circuit further held that, had it addressed those schemes, it would have found that they did not satisfy Rule 9(b) for the same reasons as the schemes it actually addressed.

2. For the most part, Caremark invoiced the Federal Plans on a weekly basis for all of the prescriptions it purportedly dispensed during that weekly billing cycle.

Whistleblowers characterize herein these types of returned drug false claims as "initially false claims," or "direct" false claims, because Caremark knew, at the time that it first invoiced the United States for those prescriptions, that those drugs had already been returned to Caremark – and yet billed the government for them anyway. The Whistleblowers further alleged that Caremark also received returned drugs *after* it had already submitted claims for payment for those drugs. The Whistleblowers alleged that, although it may have been proper for Caremark to bill the Federal Plans for those drugs that had not been returned at the time it initially billed the government for them, it nevertheless violated the FCA, because it subsequently failed to credit the Federal Plans for those drugs on subsequent invoices. These types of false claims are referred to herein as "failure to credit false claims."

The Whistleblowers provided a detailed paper trail demonstrating that Caremark actually submitted false claims to the United States for payment as part of those returned drugs schemes. The Whistleblowers further alleged in their TAC that Caremark had admitted that, at least in the situations where it re-stocked the returned drugs back into its own inventory for resale to Federal Plan members or other Caremark plan members, that it was required to refrain from billing the government in the first instance, or that it was required to subsequently issue a credit to the Federal Plans if it received the drugs after it already invoiced for them, and that it had failed and refused to do so.

In their TAC, the Whistleblowers identified approximately 20,000 prescriptions then known by the Whistleblowers where: (1) a drug was returned to Caremark by or on behalf of a Federal Plan Member; (2) the drug was then illegally (i.e., in violation of state pharmacy laws and the Contracts) re-stocked to be re-sold by Caremark; and (3) Caremark billed and invoiced the United States for those drugs, although it knew, at the time it made its claims for payment containing charges for those prescriptions, that those drugs had already been returned, or, if Caremark had already invoiced the government for that drug, Caremark failed to issue a credit to the government on a subsequent invoice. The Whistleblowers alleged that each such invoice constituted a false claim, and specifically linked each of the approximately 20,000 prescriptions to specific invoices that Caremark submitted for payment and which falsely reflected the amounts billed or owed by the United States.

2. Caremark's Fraudulent Prescription Changing Practices

The Whistleblowers also alleged that, pursuant to a contractual program referred to as its "CCM Program," Caremark agreed to provide certain purportedly "cost-saving" services (apart from the costs of the prescription drugs) to the Federal Plans in exchange for payments of millions of dollars. These "services" largely consisted of Caremark employees contacting the offices of the doctors who prescribed medications to Federal Plan Members in an attempt to gain authorization from the prescriber for Caremark to make some change to the original prescription including: reducing the number of,

or entirely eliminating, the originally authorized refills to the prescription; moving the Federal Plan Member from one drug to another or to a generic drug; changing the dosage of the submitted prescription; and changing the number of days supplied for that prescription.

The Whistleblowers alleged that to sell this CCM plan to the United States, Caremark represented that the "changed to" prescriptions would ultimately cost the Federal Plans less money than the originally submitted prescriptions. Further, the Whistleblowers alleged that, in the Federal Contracts at issue, Caremark specifically "guaranteed" that its CCM activities would result in certain minimum "savings" and that, if such guarantees were not met, Caremark was required to pay the Federal Plans monetary penalties.

Importantly, Caremark's employees were contractually required to only obtain "prescriber approval" to make changes to Federal Plan Members' prescription, i.e., only the actual prescriber could authorize a change. The Whistleblowers also alleged that Caremark was contractually prohibited from dispensing a prescription to a Federal Plan Member and from billing for that prescription, unless it constituted a "Prescription," contractually defined as only a "lawful written, electronic or verbal order of a health care practitioner licensed to prescribe medication."

However, in knowing and intentional violation of those terms, Caremark surreptitiously carried out company-wide policies pursuant to which Caremark's employees made the above-described changes to prescriptions submitted by Federal Plan Members

without first obtaining approval from the prescribers. Indeed Caremark regularly obtained "approval" from employees within prescribers' offices other than the prescribers, such as receptionists. Alternatively, Caremark simply claimed to have obtained approval where no approval was given by *anyone* — much less the prescriber. The Whistleblowers further alleged that Caremark rewarded its employees for bringing about the greatest number of such changes by awarding them cash equivalents to purchase various merchandise, electronics, trips to amusement parks, and various other valuable perks.

The Whistleblowers further alleged that Caremark's CCM practices resulted in the submission of false claims for payment. Specifically, the Whistleblowers alleged that Caremark invoiced the Federal Plans for its CCM Program services on a once-monthly basis. The Whistleblowers alleged that those invoices constituted "direct" false claims because Caremark sought payment for CCM Program services never rendered, or rendered in a fraudulent manner inconsistent with Caremark's obligations under the Contracts and applicable law — including in violation of Caremark's contractual and legal obligations to only obtain "prescriber approval" for all changes, and only to bill for "prescriptions."

In addition, in the TAC, The Whistleblowers specifically identified and described in detail dozens of representative examples of specific prescriptions changed by Caremark without prescriber approval which resulted in it submitting a false claim. In each such example, the Whistleblowers alleged, with particularity: (1) the specific prescription originally submitted; (2) the

specific change made by Caremark; (3) the date of such change; (4) that the Whistleblowers, after obtaining permission from the affected Federal Plan Member, contacted and spoke with the actual prescriber (who Caremark claimed had authorized the change); and (6) the prescriber verified that neither he nor his office authorized the changes.

B. The Course Of Proceedings

The Whistleblowers filed their original Complaint under seal on December 2, 2003. On March 30, 2004, they filed an Amended Complaint, which was unsealed on February 16, 2006. On May 30, 2006, the District Court granted Caremark's Motion to dismiss the Amended Complaint, but granted the Whistleblowers leave to re-file. *United States ex rel. Fowler v. Caremark Rx, Inc.*, No. 03 C 8714, 2006 WL 1519567 (N.D. Ill. May 30, 2006) ("*Fowler I*").

On June 23, 2006, the Whistleblowers filed their Second Amended Complaint ("SAC"). Caremark filed a Motion to Dismiss pursuant to Fed. R. Civ. P. 9(b). Caremark also moved pursuant to Fed. R. Civ. P. 12(b)(1) to dismiss for lack of subject matter jurisdiction, arguing that the Whistleblowers' Second Amended Complaint was barred by the "public disclosure bar" of the FCA.

On August 21, 2006, the District Court granted in part, and denied in part, Caremark's Motion to Dismiss the Second Amended Complaint. *United States ex rel. Fowler v. Caremark Rx, Inc.*, No. Civ. A. 03 C 8714, 2006 WL 3469537 (N.D. Ill., Aug. 21, 2006) ("*Fowler II*"). The District Court rejected Caremark's public disclosure bar

arguments, concluding that the Petitioners "are the type of whistle-blowers [the FCA] aims to encourage." *Id.* at *5

However, the District Court dismissed entirely the SAC, incorrectly concluding that the Whistleblowers did "not identify a single prescription through which Caremark perpetrated the alleged fraud. Nor do they tie a specific fraudulent transaction to an invoice submitted to the government." *Fowler II* at *6. However, the District Court further held that, because the allegations of the SAC were not "facially frivolous," its dismissal was without prejudice. (*Id.*) The District Court entered an Order granting the Whistleblowers leave to submit a proposed Third Amended Complaint. (*Id.*)

On October 16, 2006, the Petitioners filed a Motion, pursuant to Fed. R. Civ. P. 15(a), for leave to file their Third Amended Complaint, attaching a proposed Third Amended Complaint ("TAC").

Caremark filed objections, arguing that the proposed TAC did not comport with Rule 9(b). On November 30, 2006, the District Court sustained Caremark's objections and entered judgment in favor of Caremark and against the Whistleblowers, with prejudice. *See United States ex rel. Fowler v. Caremark Rx, Inc.*, No. Civ. A. 03 C 8714, 2006 WL 3469537 (N.D. Ill. Nov. 30, 2006) ("*Fowler III*"); Pet. App. B. Although the District Court finally acknowledged that the Petitioners had in fact provided examples of specific false claims, it moved the goalposts, holding that the Whistleblowers had not satisfied Rule 9(b) because they, *inter alia*, had purportedly not provided *enough* examples to prove a "pattern and

practice" of FCA violations by Caremark. *Id.* at *6; Pet. App. B at 41a-42a.

The Whistleblowers filed a timely appeal. On July 27, 2007, the United States Court of Appeals for the Seventh Circuit upheld the judgment of the District Court. 496 F.3d 730, Pet. App. A. First, consistent with the District Court's earlier holding, the Seventh Circuit held that the District Court had subject matter jurisdiction over the Whistleblowers' claims. *Id.* at 735-739, Pet. App. A at 5a-16a.

Nevertheless, relying upon a factual record that did not exist, improperly disregarding the actual factual record, and most importantly, announcing new elements that must be satisfied to plead a claim under the FCA, the Seventh Circuit upheld the District Court's refusal to grant the Whistleblowers leave to file their Third Amended Complaint on the grounds that it would be futile. Specifically, with respect to the Whistleblowers' returned drugs claims, the Seventh Circuit held that the Whistleblowers were required to, and failed to, plead and prove at the pleading stage that Caremark had *not* paid back the United States at some point in time after it initially submitted the identified false claims for payment. *Id.* at 741-742, Pet. App. A at 21a-22a. In so, holding, the Seventh Circuit ignored the undisputed and well-pled fact that there was no record evidence from which one could infer that Caremark had ever made any such re-payments to atone for its submission of false claims for payment. With respect to this and the other schemes alleged by the Whistleblowers, the Seventh Circuit, departing from the text and purpose of Rule 9(b) and the law of other Circuits, held that the

Whistleblowers failed to satisfy Rule 9(b) because they did submit evidence (at the pleading stage) that Caremark acted with "knowledge," adopting, or setting a new heightened pleading standard for state of mind under Rule 9(b). *Id.* at 742-743, Pet. App. A at 22a-24a.

On August 10, 2007, the Whistleblowers filed a timely Motion for Panel Rehearing With Suggestion for Rehearing *En Banc.* That Motion was denied without comment by the Seventh Circuit on September 7, 2007. Pet. App. C.

REASONS FOR GRANTING THE PETITION

I. The Importance Of The FCA

The FCA is the government's primary tool for combating fraud against the federal government. *See Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 792 (2000). Indeed, since the passage of the liberalizing 1986 amendments to the FCA (the "1986 amendments"), the government has recovered more than $20 billion pursuant to the FCA. *See* Taxpayers Against Fraud ("TAF");[3] *see also* Press Release By Senator Charles Grassley, *Grassley-Authored Legislation Helps Justice Department Recover $1.45 Billion This Year*, Nov. 1, 2007.[4] In fact, of the nearly $2 billion recovered by the government this year, $1.45 billion was the result of lawsuits initiated by Whistleblowers under the *qui tam* provisions of the FCA. *Id.*

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3. http://www.taf.org/statistics.htm.

4. *http://grassley.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=fc276799-1321-0e36-ba32-d94f86957981.*

The primary purpose of the 1986 amendments was to "encourage more private enforcement suits" under the FCA. S. Rep. No. 345, 99th Cong. 2d Sess. 6, *reprinted in 1986* -14- U.S. Code Cong. & Admin. News 5271, 5288-5289. Indeed, Congress sought to fight corporate fraud by fighting what it termed a "conspiracy of silence" among employees of corporations. *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1154 (3rd Cir. 1991) (quoting S. Rep. No. 345, 99th Cong. 2d Sess. 6, *reprinted in* 1986 U.S. Code Cong. & Admin. News 5271).

This Court has also long recognized the importance of the FCA. In addition to the recently considered *Sanders* and *Rockwell* cases (discussed above), this Court has granted *certiorari* in three other FCA cases in the last ten years. *See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 1158 (2005); *United States ex rel. Chandler v. Cook County, Ill.*, 538 U.S. 119 (2003); *Vermont Agency, supra*, 529 U.S. 765; *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997). Although each of these cases addressed important and contested issues relating to actions brought under the FCA, this Court has never granted *certiorari* to consider the equally important and timely questions raised in this Petition which have the potential to affect nearly every FCA case, namely: (1) whether a defendant can negate liability under the FCA where there is a theoretical possibility that it paid back, or could pay back the government at some future date, for previously submitted false claims; and (2) the proper application of Rule 9(b)'s particularity requirement to FCA cases — an issue raised in nearly every FCA action.

II. The Seventh's Circuit's Holding That The FCA Requires Proof That A Defendant *Did Not* Reimburse The Government At Some Point In Time After It Submitted A False Claim, Creates An Issue Of Extreme Importance

As discussed above, the Whistleblowers alleged that Caremark submitted false claims for payment in circumstances where it received returned drugs back from Federal Plan Members, and yet still knowingly and intentionally billed the government for those drugs ("initial false claims"), or, in other instances, failed to credit or otherwise pay back the government for those returns where it learned, after submitting a claim for payment, that the drugs had been returned ("failure to credit" or "reverse false claims"). The Whistleblowers alleged that, as a result, with respect to the initial false claims, Caremark violated § § 3729 (a)(1) and (a)(2) of the FCA, and in the case of the reverse false claims, Caremark violated § 3729 (a)(7) of the FCA.

The Seventh Circuit held that the Relators did not satisfy Rule 9(b) because (at the pleading stage no less) they did "not present any evidence *at an individualized transaction level* to demonstrate that Caremark failed to provide an appropriate refund or replacement product for a returned prescription."[5] *Fowler*, 496 F.3d at 741-

5. Notably, even though the Whistleblowers contest that such "evidence" is necessary to satisfy Rule 9(b), in their TAC, they actually did affirmatively plead that Caremark never made any such refunds or credits, or provided any replacement products in return drug situations.

742, Pet. App. A at 21a-22a.[6] The Seventh Circuit accordingly concluded that "the Relators err by assuming ... that once a prescription was returned, Caremark automatically either kept the money or continued to bill without providing an appropriate credit to the government or replacement prescription to federal employees." *Id.* Thus, under the Seventh Circuit's holding, where a relator brings claims pursuant to 31 U.S.C. § 3729(a)(1) and (a)(2) of the FCA, he/she is affirmatively required to plead and *prove* (at the pleading stage) that the defendant *did not* repay, credit, or otherwise make the government whole at some point in the future *after* the defendant initially submitted, or caused to be submitted, a false claim. In so holding, the Seventh Circuit betrayed the purpose and text of § 3729 (a)(1) and (a)(2) of the FCA, creating disastrous policy consequences and contradicting the decisions of this Court and of the other Circuits.

A. The Text Of § 3729 (a)(1) And (a)(2) Does Not Support The Seventh Circuit's Ruling

Contrary to the decision of the Seventh Circuit, there is nothing in the text of § 3729 (a)(1) and (a)(2) of the FCA that requires affirmative proof from a plaintiff-Relator that a defendant *did not* pay back the government after the defendant submitted a false claim. Pursuant to § 3729(a)(1), liability attaches where a person "knowingly presents, or causes to be presented, ... a false or fraudulent claim for payment or approval."

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6. Inexplicably, the Seventh Circuit did not apply § 3729(a)(7) to the Whistleblowers' failure to credit claims, instead incorrectly applying (a)(1) and (a)(2) to all of the claims.

Similarly, pursuant to § 3729(a)(2), liability attaches where a person "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."

Thus, there is simply no textual basis for concluding that a defendant may negate liability under these provisions by later paying back the government after first submitting a false claim. Indeed, the plain text dictates that liability attaches upon the presentation of a false claim under section (a)(1), and upon the making, using or causing to be made a false record or statement under section (a)(2).

Underscoring the fact that affirmatively proving the *absence* of subsequent reimbursement by the defendant is not required by sections (a)(1) and (a)(2), much less at the pleading stage, is the fact that this Court and other Circuits have long held that a defendant can be held liable under the FCA even if the government *never even makes a payment* in response to the submission of the initial false claim for payment. *See, e.g., Rex Trailer Co. v. United States*, 350 U.S. 148, 153 n.5 (1956); *Harrison v. Westinghouse Savannah River* Co., 352 F.3d 908, 917 (4th Cir. 2003); *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995). Accordingly, if proof of actual payment by the government in response to the submission of a false claim is not even required to trigger liability under subsections (a)(1) and (a)(2), it certainly cannot be said that proof of the absence of payment is nevertheless required, much less at the pleading stage.

B. The Purposes Of The FCA Do Not Support The Seventh Circuit's Holding

In addition to departing from the text of the FCA, the Seventh Circuit's Opinion also betrays one of the central purposes of the FCA. As discussed above, there is no dispute that the FCA serves as an indispensable tool for reimbursing the government for monies wrongfully obtained. However, that is not the FCA's sole purpose. "[O]ne of the primary purposes of the FCA [is to police] the integrity of the government's dealings with those to whom it pays money." *Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) (emphasis added) (citation omitted). Of course, the Seventh Circuit's novel holding that now permits a defendant to completely evade liability under the FCA so long as the mere possibility exists that it could repay in the future money that it wrongfully took from the government in the first instance, makes a mockery out of the billing process, completely frustrating a purpose of the FCA.

C. The Seventh Circuit's Holding Is Contrary To Sound Public Policy

The policy implications of the Seventh Circuit's additional proof requirement is staggering. As discussed above, based upon the Seventh Circuit's engrafting of new elements onto § 3729 (a)(1) and (a)(2) of the FCA, a defendant can submit a false claim with impunity so long as, sometime later down the road it credits, pays back, or otherwise makes the government whole — or, even claims that it will do so in the future. Of course, in practice, a false claim would never ripen because a

defendant could still theoretically pay the government back after the institution of a *qui tam* lawsuit, or after being confronted by the government about its fraudulent conduct. In short, leaving open the possibility for a defendant to escape liability by repaying the government after a false claim has been submitted serves to cloak a defendant with immunity in its dealings with the government. Such a result is clearly contrary to the FCA's aim of bringing wrongdoing government contractors to bear for defrauding the government.

The Seventh Circuit's new standard essentially guarantees that all but the most ethical of defendants will simply cheat the government until caught, at which point they can either pay back or otherwise make the government whole, or merely vow to do so through the early stages of litigation. Naturally, as in this case, defendants will *not* pay back the government or otherwise make it whole because it is virtually impossible for a Relator, at the pleading stage, to "prove" a negative – i.e., that the defendant *did not*, by its subsequent actions rectify its fraudulent conduct of previously submitting false claims. As this Court can plainly see, the Seventh Circuit's new interpretation of the FCA will have a profound effect on the entire enterprise of the FCA and the noble results the Act and the 1986 amendments have brought in regaining over $20 billion that was wrongfully taken from the federal coffers since 1987.

III. The Seventh Circuit's Interpretation Of Rule 9(b) Raises Issues Of Extreme Importance

Rule 9(b) is perhaps the single biggest roadblock facing *qui tam* relators today. Indeed, a Westlaw search for the terms "9(b)" and "False Claims Act" yields more than 562 results. Given the emphasis placed on Rule 9(b) by the lower courts in FCA cases, and the hurdles to pleading a claim imposed by it, it is not surprising that the fate of the Relators' TAC rested almost entirely upon the District Court's and the Seventh Circuit's respective interpretations of different aspects Rule 9(b).

In denying the Whistleblowers leave to file their TAC, the District Court found that they had not plead specific instances of fraud with sufficient particularity to satisfy Rule 9(b). *See, generally*, *Fowler III*, 2006 WL 346953; Pet. App. B. On the other hand, the Seventh Circuit did not dispute that the Whistleblowers had alleged specific instances of fraud with sufficient particularity. Rather, focusing its analysis on the FCA's requirement that a violation be made "knowingly," the Seventh Circuit improperly held that the Whistleblowers' allegations did not satisfy Rule 9(b) because:

> There is no evidence in the proposed third amended complaint that Caremark had actual knowledge of this issue or otherwise ignored or disregarded this situation. At best, the "scheme" as currently alleged by the Relators merely rises to a breach of contract dispute between the health plans, the government and Caremark.

Fowler, 496 F.3d at 743, Pet. App. A at 24a. Thus, the Seventh Circuit apparently concluded that where the

submission of false claims arises pursuant to a contractual relationship, in order to satisfy Rule 9(b) a relator must not only plead "knowledge" with particularity, but must actually provide "evidence" of such knowledge at the pleading stage. These issues should be addressed by this Court.

A. The Proper Application Of Rule 9(b)'s Requirement That Fraud Be Pled With Specificity Raises An Issue Of Exceptional Importance

1. This Court Has Never Directly Addressed The Proper Application Of Rule 9(b)'s Particularity Requirements

Since its adoption in 1938, this Court has never granted certiorari for the purpose of determining the proper application of Rule 9(b). Indeed, the Court has mentioned Rule 9(b) in only a handful of cases over that time. *See Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit*, 507 U.S. 163 (1993); *Swierkiewicz v. Sorema*, 534 U.S. 506 (2002); *Klapprott v. United States*, 335 U.S. 601 (1949). Notably, none of these cases addressed application of Rule 9(b)'s particularity requirement. The closest this Court has come to addressing 9(b)'s particularity requirement was in *Rotella v. Wood*, 528 U.S. 549 (2000), which concerned when the statute of limitations begins to run for RICO claims. In rejecting the argument that the limitations period begins upon discovery of the pattern of racketeering activity, the Court briefly touched on Rule 9(b), noting that it should be applied flexibly, "allowing pleadings based upon evidence reasonably expected

after further investigation or discovery." *Id.* at 560. The time is ripe for the Court to provide further guidance to the lower courts applying Rule 9(b) to FCA cases.

2. This Court's Lack Of Guidance Has Led To Confusion In The Lower Courts As To The Proper Application Of Rule 9(b)'s Requirement That, In Averments Of Fraud, The Circumstances Must Be Alleged With Particularity

In general, lower courts applying Rule 9(b) have noted various purposes for application of the Rule in fraud cases including: (1) to protect the defendant's reputation from harm; (2) to minimize "strike suits" and "fishing expeditions;" and (3) to provide notice of the claim to the adverse party. *See, e.g., Viacom Inc. v. Harbridge Merchant Services, Inc.*, 20 F.3d 771, 777 (7th Cir. 1994); *United States v. Martin-Baker Aircraft Co., Ltd.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004); *Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003); *United States ex rel. Clausen v. Laboratory Corp.*, 290 F.3d 1301, 1310 (11th Cir. 2002). In furtherance of those purposes, the lower courts have nearly unanimously adopted what some refer to as a "journalistic approach," which requires a plaintiff to satisfy the Rule by identifying the "who, what, when, where, and how" of the alleged fraud. *See, e.g., Kanter v. Barella*, 489 F.3d 170, 175 (3rd Cir. 2007); *Tricontinental Indust. v. PWC.*, 475 F.3d 824 (7th Cir. 2007); *United States ex rel. v. Regence Bluecross*, 472 F.3d 702 (10th Cir. 2006). While one might expect such unanimity to result in a uniform application of Rule 9(b), in fact, quite the opposite has been true. In practice, the

lack of guidance from this Court regarding the proper application of Rule 9(b) (especially in FCA actions) has led to the inconsistent and wildly incoherent application of that Rule by the lower courts. However, even from this mosaic of Rule 9(b) applications, three basic and standards can be gleaned.

a. Some Courts Apply A Flexible Standard, Holding That A Description Of The Fraudulent Scheme Satisfies Rule 9(b)

Many courts, when faced with Rule 9(b) challenges to FCA complaints, have held that the plaintiff need only provide a sketch of the scheme without identifying any specific false claims. This approach best adheres to the purposes of Rule 9(b), especially, where as in the present case, the Relators' allegations concern a system of corporate fraud; grounded in corporate policies and procedures; occurring over a multi-year period; and perpetrated at several facilities in multiple states.[7]

Emblematic of this approach is *United States ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204 (E.D. Tex. 1998). In *Johnson*, the plaintiffs-*qui tam* relators brought an action under the FCA alleging that the defendant made false statements on monthly royalty reports to the

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7. *See, e.g., United States ex rel. Glaser v. Wound Care Consultants, Inc.*, 1:05-cv-0573-LJM-WTL, 2007 WL 837203 (S.D. Ind. Mar. 12, 2007); *In re Pharmaceutical Indust. Avg. Wholesale Price Litig.*, 307 F. Supp. 2d 196, 208 (D. Mass. 2004); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 333 (D. Conn. 2004); *United States ex rel. Mayman v. Martin Marietta Corp.*, 894 F. Supp. 218, 223 (D. Md. 1995); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001).

government without alleging any details of any specific report. The defendants moved to dismiss the complaint under Rule 9(b), arguing that the allegations lacked the "particulars of time, place, and contents of the false representations as well as the identity of the persons making the misrepresentation and what he obtained thereby." *Id.* at 206. The defendants further argued that the complaint did not identify which specific defendants committed which specific fraudulent activity, nor when the specific conduct occurred, nor did it "identify any specific royalty amounts withheld . . . [nor] even one particular oil value improperly used." *Id.* In short, as the *Johnson* court noted, "the defendants [argued that] the [*qui tam*] relators must allege facts with excruciating exactness as to the times, locations, and persons involved in each and every statement plead as well as each statements' contents." *Id.*

In rejecting that argument, the *Johnson* court noted that, although the "[c]omplaint must contain the 'who, what, when, where, and how' of the false representation," Rule 9 does not require fact pleading and must be construed to do substantial justice. *Id.* The *Johnson* court further found that

> it is only common sense that the sufficiency of pleadings under Rule 9(b) may depend upon 'the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading.'

Id. The court further recognized that, "similarly, it has been widely held that where the fraud allegedly was

complex and occurred over a period of time, the requirements of Rule 9(b) are less stringently applied." *Id.* The court in *Johnson* thus held that, to approach the issue otherwise, "would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection." *Id.*

Two other notable cases applying this liberal approach to Rule 9(b) should be contrasted with the instant case. First, in *United States ex rel. Salmeron v. Enterprise Recovery Sys., Inc.*, 464 F. Supp. 2d 766, 768 (N.D. Ill. 2006), a decision ironically issued from the same District Court as the present case, and *on the very same day*, took a completely different approach which, had it been applied in this case, would have saved the Whistleblowers' TAC. Specifically, the *Salmeron* court held that a FCA action with infinitely less specificity than that provided by the Relators in the present case passed muster under Rule 9(b), finding that:

> while there is a good deal of caselaw that speaks of a journalistic-type approach to [Rule 9's] requirement of pleading 'with particularity,' that locution really does not fit well in dealing with extended fraudulent schemes involving a large volume of transactions — it must be remembered that what Rule 9(b) mandates particularity about are "the *circumstances* constituting fraud" . . . by supplying just such a general outline of the "circumstances constituting fraud.

Accordingly, it was only by the *fiat* of judicial assignments that the Whistleblowers' claims in the

present case failed where the *Salmeron* plaintiff was permitted to proceed with his FCA action on the same day in the same courthouse. In short, without guidance from this Court, the District Court (and later the Seventh Circuit) applied an entirely different interpretation of Rule 9(b) to the Relators' FCA claims than that applied by the court in *Salmeron*.

Finally, another particularly notable case illustrating the inconsistent approach taken to Rule 9(b) in the lower courts is *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430 (E.D. Pa. 2004) ("*Medco*"). That action involved relators who worked at Caremark's main competitor, and who alleged similar schemes to those pled in the instant case. In *Medco*, the District Court ruled that the complaint, which contained infinitely less specificity than provided by the Whistleblowers in this case, satisfied Rule 9(b) despite the fact that not a single specific false claim prescription was identified. The approach to interpreting Rule 9(b) embodied by the above cases will be referred to below as the "flexible approach."

b. Some Courts Hold That Identification Of Specific False Claims Submitted As A Result Of The Fraudulent Scheme Is Required

Another line of cases holds that it is insufficient for Rule 9(b) purposes to provide detail regarding the defendant's fraudulent schemes, and that the relator must instead provide detailed information regarding

specific false claims that the defendant submitted as a result of such schemes.[8] This line of cases is illustrated by *United States ex rel. Karvelas* v. *Melrose Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004), where the court held that:

> Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action.

This approach will be referred to below as the "specific instances" approach.

c. Some Courts Disregard Express Allegations Unless The Complaint Contains Sufficient "Indicia Of Reliability"

A third line of cases has rejected the "flexible approach" and even the "specific instances" approach as too broad. Rather, this line of cases holds that the

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8. *See*, e.g., *United States ex rel. Rost v. Pfizer, Inc.* __ F.3d __, 2007 WL 3379842 (1st Cir. Nov. 15, 2007); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, __ F.3d __, 2007 WL 2492439, at *7 (6th Cir. Sept. 6, 2007).

relator's express allegations that a claim was submitted may be disregarded if the Court determines at the pleading stage that such allegations are not sufficiently reliable. This "indicia of reliability" test originated with the Eleventh Circuit's decision in *United States ex rel. Clausen* v. *Laboratory Corp. of America*, 290 F.3d 1301 (11th Cir. 2002).

In *Clausen*, the relator alleged that the defendant routinely submitted false claims to the Medicare program for laboratory tests that were unnecessary, duplicative, or otherwise improper. In addition to alleging the details of the fraudulent scheme, the complaint also identified a large number of specific tests that were performed; provided the patient initials, the date of the test, and the type of test; described why the tests were improper; and expressly alleged that a claim for payment was submitted on the date of the test or within a few days thereafter. *Id.* at 1304-1306 and n.7. Notwithstanding that level of detail, the Eleventh Circuit disregarded the relator's express allegations regarding the submission of claims, holding that:

> Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government. . . . [I]f Rule 9(b) is to be adhered to, *some indicia of reliability must*

> *be given in the complaint to support the allegation of an actual false claim for payment being made to the Government.*

Id. at 1311 (emphasis added).

Thus, rather than taking the relator's allegations as true, the *Clausen* Court crossed over into full-fledged fact-finding at the pleading stage. Specifically, noting that the relator was not an employee of the defendant, and assumed that, being a "corporate outsider," the relator was "not . . . privy to [the defendant's] policy manuals, files and computer systems," the *Clausen* Court was skeptical as to whether the Relator was truthful. *Id.* at 1302-03, 1312, 1314.

Seizing upon this novel interpretation of Rule 9(b), several Courts have carried the indicia of reliability test even further, holding that only an employee of a company who had personal involvement in the actual submission false claim i.e. a billing department employee, can possess sufficient reliability that a claim was actually submitted. *See, e.g.*, *See, e.g.*, *United States ex rel. Joshi* v. *St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006); *United States ex rel. Corsello v. Lincare, Inc.*, 438 F.3d 1008, 1013 (11th Cir. 2005). This approach will be referred to below as the "billing-employee only approach."

3. The "Flexible Approach" To Rule 9(b)'s Particularity Requirement Is The Only Approach That Properly Meets The Goals Of Rule 9(b) And The FCA

The flexible approach discussed above is the only interpretation of 9(b) that not only sufficiently protects a defendant's interests, but which does not also frustrate the purposes of the FCA to encourage more private enforcement and this Court's previous statements in *Rotella*, *supra*, 528 U.S. at 650, that Rule 9(b) should be applied flexibly. As the cases cited above applying the "flexible approach" have noted, at least in schemes which are complex and occur over a period of time, advising a defendant of how a scheme gives a defendant a fair opportunity to defend itself against allegations of fraud. *See, e.g.*, *Salmeron*, 464 F. Supp. 2d 766. On the other hand, "to approach the issue otherwise would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection." *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. at 333.

Indeed, the strict "specific instances" and "billing-employee only" approaches are entirely unrealistic and directly contradict the 1986 amendments, which sought to increase the types of persons who could serve as relators and to encourage them to bring forth evidence of fraud. Indeed, in a large corporation such as Caremark, the persons who possess knowledge of the fraudulent activity being perpetrated at the company sites or in the field (or, as in the present case, at the company's pharmacies), and who also actually participate in getting the bills out to the government are as common

as unicorns — that is to say, they likely do not exist. Accordingly, under the narrow interpretations of Rule 9(b) the more diffuse a defendant's billing operation from its wrongful activities, the safer a defendant will be from facing liability from the FCA.

Indeed, were such a standard adopted it would be easy to quantify the results by simply reviewing the cases brought pursuant to the FCA and subtracting the dollar amounts from those involving relators who were not involved in billing. For example, the relators in *Medco*, 336 F. Supp. 2d 430, presented many of the very same schemes as alleged by the Whistleblowers in the present case. The *Medco* relators were not involved in Medco's billing department or in the billing process in any way, yet they and the government settled with the Medco for $163 million.[9] However, under the restrictive approaches, the claims in *Medco* would never have survived Rule 9(b) scrutiny and those monies would have remained with the wrongdoer. Clearly, such a result is not what Congress intended when it amended the FCA in 1986 to increase *qui tam* enforcement of the Act.

B. The Issue Of Whether Rule 9(b) Requires State Of Mind To Be Pled With Specificity (Or Proven, As The Seventh Circuit Held) Is An Issue Of Exceptional Importance Which Is Subject To Conflict Among The Circuits

The FCA imposes liability, *inter alia*, on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval."

9. *See* http://www.taf.org/top20.htm at #19.

31 U.S.C. § 3729(a)(1). With respect to the "knowing" requirement, the FCA specifically provides that "no proof of specific intent to defraud is required," and that a person acts knowingly if he acts in "deliberate ignorance" or in "reckless disregard" of the truth or falsity of information. 31 U.S.C. § 3729(b).

As discussed above, although Rule 9(b) requires specificity in pleading regarding the circumstances of any averments of fraud, pursuant to that same Rule, "malice, intent, knowledge, and other condition of mind of a person may be averred generally." Although this text may appear straightforward, the Circuits are hopelessly split over what it exactly means to plead state of mind "generally." Indeed, in this case, the Seventh Circuit required evidence of knowledge at the pleading stage.

1. This Court Has Never Addressed Whether Rule 9(b) Requires That State Of Mind Must To Be Pled With Specificity

In *Tellabs v. Makor Issues & Rights*, __ U.S. __, 127 S. Ct. 2499, 2507 (2007), this Court, in the context of addressing the pleading standard under the Private Securities Litigation Reform Act of 1995 (PSLRA) for securities fraud actions brought pursuant to § 10(b) of the Securities Exchange Act of 1934, briefly acknowledged that there is a debate as to whether Rule 9(b), which previously governed the pleading of such actions, requires a plaintiff to plead *scienter* with heightened specificity or whether a plaintiff could simply make the plain allegation that a defendant acted with *scienter*. Specifically, noting that, pursuant to the plain

language of Rule 9(b), "malice, intent, knowledge, and other condition of mind of a person, may be averred generally," and that the Circuits diverge on exactly what "averred generally" requires, this Court pondered the question of whether plaintiffs [could] allege the requisite mental state "simply by stating that scienter existed," or whether they were required to "allege with particularity facts giving rise to an inference of *scienter*." *Id.* __U.S. at __; 127 S. Ct. 2499. However, pondering that issue was as far as this Court went in *Tellabs*. Because the enactment of the PSLRA removed § 10(b) actions from the realm of Rule 9(b) in favor of its own more explicit provisions regarding the pleading of scienter in such cases, this Court tantalizingly left unaddressed the issue of Rule 9(b)'s requirements for pleading state of mind. *Id.*

Although this issue was first raised with respect to securities fraud cases, it has been addressed by the Circuits with respect to the FCA as well, in cases apart from the present case. *See, e.g., United Stated ex rel. Willard v. Humana Health Plan*, 336 F.3d 375, 384-85 (5th Cir. 2003); *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2nd Cir. 1995); *United States ex rel. Smith v. Yale University*, 415 F. Supp. 2d 58, 83 (D. Conn. 2006); *Medco, supra.*, 336 F. Supp. 2d 430; *United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313 (S.D.N.Y. July 29, 2004). Given the Seventh Circuit's ruling in the present case that the Relators failed to prove (or plead with requisite specificity) that Caremark "knowingly" violated the provisions of the FCA, this case provides this Court with an excellent opportunity to finally address this issue.

a. Some Courts Interpret Rule 9(b) As Requiring Only A Statement That The Defendant Acted With The Required Mental State

As discussed above, some of the Circuits have interpreted Rule 9(b)'s allowance that state of mind may be averred "generally" to mean that the plaintiff need only include a mere statement in its complaint that the defendant acted with the requisite state of mind. *See, e.g., In re GlenFed, Inc. Securities Litigation*, 42 F.3d 1541, 1546-1547 (9th Cir. 1994) (en banc))

For example, in *GlenFed*, the Ninth Circuit became the first Circuit to hold plaintiffs may aver scienter generally, just as the Rule states — that is, simply by alleging that scienter existed, as opposed to the Second Circuit's view that plaintiffs in securities fraud cases must plead facts giving rise to a "strong inference of fraudulent intent." *Id.*

In reaching that conclusion, the *GlenFed* court focused heavily on the text and origins of the Rule:

> The second sentence of Rule 9(b) is very clear: 'Malice, intent, knowledge, and other condition of mind may be averred generally.' The model for Rule 9(b), Order 19, Rule 22 of the English Rules of Practice of 1937, is clearer still:
>
> 'Wherever it is material to allege malice, fraudulent intention, knowledge, or other condition of the mind of any person, it shall be sufficient to allege the same as a fact

> *without setting out the circumstances from which the same is to be inferred.'*

Id. (*citing* The Annual Practice, Order 19, Rule 22 (1937) (emphasis in original)). Accordingly, the *GlenFed* court concluded that to require a plaintiff to set forth the circumstances from which state of mind could be inferred would directly conflict with the English source of Rule 9(b).

b. Some Circuits Have Required Plaintiffs To Plead Specific Facts That Create A "Strong Inference" That The Defendant Acted With The Requisite State Of Mind

A number of Circuits have abandoned the text and underlying history of Rule 9(b), and instead have sought to impose policy through a heightening of that Rule's allowance that state of mind may be averred generally. For example, in the Second Circuit, "although scienter, or fraudulent intent, may be pled generally, a plaintiff still must allege facts that give rise to a 'strong inference' of fraudulent intent." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994); *see, also, e.g., United Stated ex rel. Willard v. Humana Health Plan*, 336 F.3d 375, 384-85 (5th Cir. 2003); *DiLeo v. Ernst & Young*, 901 F.2d 624, 629 (7th Cir. 1990), *cert. denied*, 498 U.S. 941 (1990). Courts applying this heightened standard have typically justified their departure from the text and history of Rule 9(b) by concluding that to hold otherwise would encourage "strike suits" prevention of which is a goal of Rule 9(b). *See FedGlen*, 42 F.3d at 1558, 1555 . (Norris, J. concurring) (citation omitted).

2. This Court Should Adopt The 9th Circuit's Plain Text Interpretation

The plain text interpretation of Rule 9(b) provides a better approach to interpretation of that Rule. Even if the prevention of strike suits is a proper aim of Rule 9(b), courts are "not permitted to add new requirements to Rule 9(b) simply because we like the effects of doing so," because that is "a job for Congress, or for the various legislative, judicial, and advisory bodies involved in the process of amending the Federal Rules." *GlenFed*, 42 F.3d at 1546; *see also Leatherman*, *supra*, 507 U.S. 163, 168, (1993). Further, the justification that specificity in pleading state of mind is necessary to prevent "strike suits" ignores the fact that the circumstances of *fraud* must still be plead with specificity.

Not only is a heightened standard not necessary, adoption of such a standard would frustrate Congress' goal of seeking more *qui tam* enforcement of the FCA. Indeed, "the characterization of a state of mind, after all, does not lend itself to detailed pleading." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 227-228 (1st Cir. 2004). Finally, it is important to note that, even if this Court were to accept the position that a plaintiff must plead facts from which state of mind can be strongly inferred, the Seventh Circuit not only simply ignored such facts as set forth in the Relators' TAC, but also went well beyond the heightened approach, requiring not just facts from which an inference can be made, but actual *evidence*, at the pleading stage. To resolve the conflict in the Circuits, this Court should reject the Second Circuit's "strong inference" approach and the Seventh Circuit's extreme

"evidence" approach, and should instead adopt the Ninth Circuit's position that a mere statement that the defendant possessed the requisite state of mind is sufficient to satisfy Rule 9(b).

Given the FCA's importance as the nation's primary tool for combating government fraud, and given the enormous impact Rule 9(b) has had on cases brought under the FCA, this Court should grant *certiorari* to clarify the proper relationship between Rule 9(b) and the False Claims Act.

CONCLUSION

For all of the foregoing reasons, this Court should grant the Petition for a Writ of *Certiorari* and reverse the Seventh Circuit Court of Appeals.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT DECIDED JULY 27, 2007

In the
UNITED STATES COURT OF APPEALS
for the Seventh Circuit

No. 06-4419

UNITED STATES *ex rel.* MICHAEL FOWLER, PEPPI FOWLER, VICTOR CORTES, and DANNY NEVAREZ,

Plaintiffs-Appellants,

v.

CAREMARK RX, L.L.C., and CAREMARK INC.,

Defendants-Appellees.

Argued June 6, 2007—Decided July 27, 2007

Before RIPPLE, KANNE, and EVANS, *Circuit Judges.*

KANNE, *Circuit Judge.* The plaintiff—Relators are employees of Caremark. They filed a *qui tam* action under the False Claims Act. 31 U.S.C. § 3729 *et seq.* The district court held that subject matter jurisdiction existed but dismissed the complaint on the merits. On appeal, the Relators argue that the district court erred in dismissing the case while Caremark argues that the case should have been dismissed for want of subject

matter jurisdiction. We conclude that subject matter jurisdiction exists and we affirm the judgment of the district court on the merits.

I. HISTORY

The United States government, like many employers, provides health insurance benefits to its employees. The government contracts with various private health insurance plans. Federal employees are able to choose among these private health insurance plans. Both the United States and individual federal employees make premium payments to the plans for the health coverage.

Many health plans provide prescription drug coverage as part of their benefit package for the participating federal employees. In turn, a number of these plans contract with Caremark to provide the prescription drug benefits provided under their respective plans. Caremark ultimately receives payment from the federal government and its employees for the prescription drugs and related services provided under the plans.

The Relators, (we call them Relators, they call themselves Whistleblowers), were employed by Caremark at two of its prescription drug processing facilities. The Relators brought a False Claims Act suit on behalf of the United States alleging that Caremark engaged in six fraudulent schemes: (1) failing to provide a credit for returned prescription drugs; (2) changing

prescriptions without proper approval; (3) misrepresenting the savings obtained from its recommendations; (4) failing to substitute a generic version of "Prilosec;" (5) failing to credit for prescriptions lost in the mail; and (6) manipulating the mandatory times for filing prescriptions.

The Relators filed their original complaint under seal in December 2003. An amended complaint was also filed under seal in March 2004. In July 2004, the United States Attorney's Office for the Northern District of Illinois contacted Caremark and asked it to cooperate in an investigation of Caremark's business practices. From October 2004 through January 2006, Caremark disclosed in excess of 113,000 pages of documents to the U.S. Attorney's Office. These documents included Caremark's contracts with the health insurance plans serving federal employees, invoices, quarterly reports, Caremark's internal reports, memoranda and training procedures. In January 2006, the government declined to intervene in this case and the case was unsealed by the district court in February 2006. In April and May 2006, the Relators obtained discovery materials from both Caremark and the U.S. Attorney's Office.

In May 2006, the district court granted Caremark's motion to dismiss the first amended complaint holding that the complaint failed to meet the heightened pleading requirements of Rule 9(b). *United States ex rel. Fowler v. Caremark RX, Inc.*, 03 C 8714, 2006 WL 1519567 (N.D.Ill. May 30, 2006). The Relators were granted leave to file a second amended complaint which they did in June 2006.

Caremark then argued that case should be dismissed pursuant to the jurisdictional bar contained in 31 U.S.C. § 3730(e)(4). Caremark's position was that the Relators' second amended complaint was based on publicly disclosed information and the Relators were not the original source of this information. The district court rejected Caremark's jurisdictional argument and held that the Relators met the requirements of § 3730(e)(4). *United States ex rel. Fowler v. Caremark RX, Inc.*, No. 03 C 8714, 2006 WL 2425331, at *4-6 (N.D.Ill. Aug.21, 2006).

However on the merits, the district court held that despite increasing in size, the second amended complaint failed to meet the heightened pleading requirements of Rule 9. The second amended complaint consisted of 514 paragraphs spanning over 178 pages and also had over 1000 pages of attached exhibits. *Id.* at *3. The district court explained that despite its length, the second amended complaint failed to "identify a single prescription through which Caremark perpetrated the alleged fraud. Nor do they tie a specific fraudulent transaction to an invoice submitted to the government. . . . [N]otice [sufficient to satisfy Rule 9(b)] is woefully inadequate where, as here, plaintiffs allege only generalized schemes and fail to specify a single false claim." *Id.* at *6-7.

The Relators were then given an opportunity to seek leave to file a third amended complaint. However, the district court warned the Relators that the case could be dismissed in its entirety if they failed to provide a proposed third amended complaint that complied with the federal rules. The Relators then tendered their proposed third

amended complaint and sought leave to file the complaint. The district court rejected the proposed third amended complaint holding that it failed to meet the requirements of Rule 9(b). *United States ex rel. Fowler v. Caremark RX, Inc.*, 03 C 8714, 2006 WL 3469537 (N.D.Ill. Nov.30, 2006). The district court, pursuant to Rule 15(a), denied the Relators' request to file the new amended complaint and entered a judgment dismissing the case in its entirety.

II. ANALYSIS

A. The Jurisdictional Bar of 31 U.S.C. § 3730(e)(4)

Caremark argues that the district court lacked subject matter jurisdiction, pursuant to the jurisdictional bar set forth in § 3730(e)(4), because the Relators' claims are based on publicly disclosed information and the Relators are not the original source of this information. The Supreme Court has recently determined that § 3730(e)(4) is a jurisdictional requirement implicating subject matter jurisdiction and therefore no cross-appeal from Caremark is required. *Rockwell Int'l Corp. v. United States*, __ U.S. __, 127 S.Ct. 1397, 1405-07, 167 L.Ed.2d 190 (2007); *see generally Luna v. United States*, 454 F.3d 631, 635 (7th Cir.2006) (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514, 126 S.Ct. 1235, 1244, 163 L.Ed.2d 1097 (2006) (noting that a cross-appeal is not required when a party is contesting subject matter jurisdiction)); *McCready v. White*, 417 F.3d 700, 702 (7th Cir.2005) ("Ensuring the existence of subject matter

jurisdiction is the court's first duty in every lawsuit.") (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998)). We note that the Relators' proposed third amended complaint is the controlling document to be considered by this court. "[W]hen a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction." *Rockwell*, 127 S.Ct. at 1409 (citing *Wellness Cmty.-Nat'l v. Wellness House*, 70 F.3d 46, 49 (7th Cir.1995); *Boelens v. Redman Homes, Inc.*, 759 F.2d 504, 508 (5th Cir.1985)).

Title 31, United States Code, Section 3730(e)(4) states:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the

> Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4). "The bar is designed to deter parasitic *qui tam* actions.... [O]nce information becomes public, only the Attorney General and a relator who is an 'original source' of the information may represent the United States." *United States ex rel. Gear v. Emergency Med. Assoc. of Illinois, Inc.*, 436 F.3d 726, 728 (7th Cir.2006).

"The inquiry into whether a court may hear a qui tam relator's claim has three parts: (1) Have the allegations made by the plaintiff been 'publicly disclosed'? (2) If so, is the lawsuit 'based upon' that publicly disclosed information? (3) If so, is the plaintiff an 'original source' of the information?" *United States ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 859 (7th Cir.1999) (citing *United States ex rel. Cooper v. Blue Cross and Blue Shield of Florida, Inc.*, 19 F.3d 562, 564 n. 4 (11th Cir.1994)); *see also Gear*, 436 F.3d at 728; *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir.2003).

Before we begin the analysis, it should be noted that there are three types of information in the Relators' possession in this case. First is the Relators' "inside" information that they obtained during their work at Caremark. Second is the information disclosed by Caremark directly to the Relators. Third is the information disclosed by Caremark to the U.S.

Attorney's Office and then passed from the U.S. Attorney's Office to the Relators.[1]

Issue 1: Have the Allegations made by the Plaintiff been "Publicly Disclosed"?

"A 'public disclosure' exists under § 3730(e)(4)(A) when the critical elements exposing the transaction as fraudulent are placed in the public domain." *Feingold*, 324 F.3d at 495 (citing *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512 (8th Cir.1994); *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C.Cir.1994)). "The point of public disclosure of a false claim against the government is to bring it to the attention of the authorities, not merely to educate and enlighten the public about the dangers of misappropriation of their tax money." *Mathews*, 166 F.3d at 861.

"Disclosure of information to a competent public official about an alleged false claim against the government [is a] public disclosure within the meaning

1. The record is somewhat limited as to the scope of the U.S. Attorney's Office's investigation. It is clear that U.S. Attorney's Office contacted Caremark to investigate Caremark's business practices and Caremark provided information in return. This information was then disclosed by the U.S. Attorney's Office to the Relators. The record does not reflect, however, whether the U.S. Attorney's Office was engaged in a civil or criminal investigation. Specifically, the record does not tell us whether a grand jury was involved in the investigation. Grand juries, of course, are governed by Rule 6 of the Federal Rules of Criminal Procedure including the secrecy requirements of Rule 6(e)(2).

of § 3730(e)(4)(A) when the disclosure is made to one who has managerial responsibility for the very claims being made." *Id.* The more open a public disclosure, the less any specific public official needs to be informed. *Id.* Conversely, "[i]f the disclosure is made . . . to precisely the public official responsible for the claim, it need not be disclosed to anyone else to be [a] public disclosure within the meaning of the Act." *Id.* And, of course, "disclosure to the government by a *qui tam* plaintiff of the information on which the complaint is based, as mandated in § 3730(a)(2), is not 'public disclosure' under § 3730(e)(4)(A)." *Id.* at 862.

Caremark's disclosure of information to the U.S. Attorney's Office during the government's investigation of Caremark's business practices qualifies as a public disclosure of the Relators' allegations. The scope of the investigation involved whether Caremark defrauded the federal government through its participation in the federal employee health insurance programs. The U.S. Attorney is the primary legal representative of the United States within his or her respective district, 28 U.S.C. § 547, and would be the public official responsible for bringing criminal or civil claims against Caremark on this issue. Thus, the Relators' allegations have been publicly disclosed.

Appendix A

Issue 2: Is the Lawsuit "Based Upon" that Publicly Disclosed Information?

"[A] lawsuit is based upon public[ly] disclose[d information] when it 'both depends essentially upon publicly disclosed information and is actually derived from such information.' " *Feingold*, 324 F.3d at 497 (quoting *Mathews*, 166 F.3d at 864). Caremark notes that our standard conflicts with the standard adopted by the majority of circuits and argues that we should reconsider our position in light of this conflict.

The majority of circuits apply the standard "that a qui tam action is 'based upon' a public disclosure when the supporting allegations are 'the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information.' " *Mathews*, 166 F.3d at 863 (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir.1992)) (citing *United States ex rel. Kreindler & Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1158 (2d Cir.1993); *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 652-55 (D.C.Cir.1994); *United States ex rel. McKenzie v. BellSouth Telecomm., Inc.*, 123 F.3d 935, 940 (6th Cir.1997); *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1417 (9th Cir.1992); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 552 (10th Cir.1992); *United States ex rel. Cooper v. Blue Cross and Blue Shield of Florida, Inc.*, 19 F.3d 562, 566-67 (11th Cir.1994)); *see also United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334-35 (3d Cir.2005); *Federal Recovery Servs. v. United States*, 72 F.3d 447,

451 (5th Cir.1995); *United States ex rel. Minnesota Assoc. of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1044-47 (8th Cir.2002). In *Mathews*, we declined to adopt the majority standard and instead adopted our current standard from the Fourth Circuit's decision *See Mathews*, 166 F.3d at 863 (citing 21 F.3d 1339, 1347-48 (4th Cir.1994)).

In *Mathews*, we explained that the Fourth Circuit's standard of " 'based upon' is . . . better on the grounds both of plain meaning and public policy." *Id.* The plain language argument is that " 'based upon' does not mean 'similar (even identical) to' but 'derived from.' " *Id.* (quoting *Siller*, 21 F.3d at 1347-48). The public policy justification is that "information which happens to be similar or identical to publicly disclosed allegations or transactions, but which derives from some other source than the public disclosure, is not parasitic, and should not be barred by a provision meant to bar parasitic lawsuits." *Id.* (quoting *Siller*, 21 F.3d at 1348).

In *United States ex rel. Mistick PBT v. Housing Auth. of the City of Pittsburgh*, the Third Circuit analyzed the circuit split and concluded that there was "merit" on both sides of the split. 186 F.3d 376, 386 (3d Cir.1999) (Alito, J.). According to the *Mistick* court, although the minority standard was a more faithful plain language interpretation, the interpretation would render the "original source" exception largely superfluous. *Id.* Thus, the circuit split was framed as "a clash between two textual arguments concerning the meaning of 31 U.S.C. § 3730(e)(4)(A): one based on the ordinary

meaning of the phrase 'based upon' and one based on the precept that a statute should be construed if possible so as not to render any of its terms superfluous." *Id.* at 387 (citations omitted). Citing various drafting errors in the statute, the Third Circuit determined that "[t]he inescapable conclusion is that the qui tam provision does not reflect careful drafting [and therefore] we are hesitant to attach too much significance to a fine parsing of the syntax." *Id.* at 388. Consequently, it rejected the plain language interpretation of the minority standard and determined the majority standard to be superior.

Then-Chief Judge Becker dissented from the *Mistick* decision. He noting that (1) traditionally courts defer to the plain language interpretation of statutes, (2) there were several plausible situations in which the plain meaning interpretation would not make the "original source" clause superfluous, (3) the plain meaning interpretation was consistent with how Congress had used "based upon" in another statute, and (4) the plain language interpretation was consistent with both the False Claims Act's underlying policy and legislative history. *Id.* at 395-403 (Becker, C.J., dissenting).

We reject Caremark's invitation to alter our position and reaffirm our adherence to the standard that "[a] lawsuit is based upon public[ly] disclose[d information] when it both depends essentially upon publicly disclosed information and is actually derived from such information." *Feingold*, 324 F.3d at 497. "In a statutory construction case, the beginning point must be the

language of the statute, and when a statute speaks with clarity to an issue judicial inquiry into the statute's meaning, in all but the most extraordinary circumstances, is finished." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475, 112 S.Ct. 2589, 120 L.Ed.2d 379 (1992) (citing *Demarest v. Manspeaker*, 498 U.S. 184, 190, 111 S.Ct. 599, 112 L.Ed.2d 608 (1991)). Both the majority and minority standard have rallied powerful arguments to their respective sides, but the minority standard holds the trump card, the plain language interpretation. We may be in the minority, but we will not jettison a standard when that standard includes an appropriate plain language interpretation of the statute.

Returning to the jurisdictional analysis, we must determine whether the Relators' proposed third amended complaint (1) depends essentially upon publicly disclosed information and (2) is actually derived from such information. *Feingold*, 324 F.3d at 497. The Relators' proposed third amended complaint will not meet the jurisdictional bar of § 3730(e)(4) if the Relators used materials that they received from the U.S. Attorney's Office. However, the complaint will meet the jurisdictional requirement if it is only based on other materials such as the Relators' "inside" knowledge that they obtained while working at Caremark and Caremark's disclosures made directly from Caremark to the Relators.

In its review of the second amended complaint, the district court determined that the Relators based their

complaint on their "inside" information and information obtained directly from Caremark's direct disclosure to the Relators. Thus, jurisdiction was present, according to the district court because there was no evidence of information being used from the U.S. Attorney's Office's disclosure. Of course, the proposed third amended complaint is the controlling document to be considered because the district court has dismissed the second amended complaint on Rule 9 grounds, and now the Relators seek leave to file their proposed third amended complaint. However, based on the fact that the Relators' practice has been to build current complaints off of prior complaints, and Caremark has not pointed to any indication in the proposed third complaint that the U.S. Attorney's Office material was used in any way to construct the proposed complaint, we conclude that the proposed third amended complaint is not actually derived from any publicly disclosed information provided by Caremark to the U.S. Attorney's Office and then passed onto the Relators.

Caremark has not pointed to specific items in the complaint that it says comes from the U.S. Attorney's Office's disclosure. Instead, Caremark's position is that the U.S. Attorney's Office disclosure, and the discovery disclosure it made directly to the Relators, consist essentially of identical information. Thus, Caremark argues that it is irrelevant whether the Relators faithfully limited themselves to the discovery disclosures that they received directly from Caremark and abstained from including the U.S. Attorney's Office material in the complaint. Ultimately, according to Caremark, it is all

the same material, regardless of which copy was used by the Relators in preparing their proposed third amended complaint.

At first glance, there is logic to Caremark's position. The argument raises the question of what is the legal importance of whether the Relators took their information for the complaint from Caremark's disclosure or the U.S. Attorney's Office's disclosure? It is the same material after all. However, what this argument really does is return us to Caremark's prior argument that we should abandon our current standard and instead adopt the standard from the majority of other circuits. And as we discussed above, we are unwilling to do this.

Congress said that, "No court shall have jurisdiction over an action under this section *based upon the public disclosure* of allegations or transactions . . ." 31 U.S.C. § 3730(e)(4)(A) (emphasis added). Congress *did not* say, "No court shall have jurisdiction under this section based upon the public disclosure of allegations or transactions *or material that is the same or substantially the same as the public disclosure. . . .*"

This is more than a mere blind adherence to the plain language of the statute. Congress is trying to balance two policies in this statute. On one side, Congress wants insiders to come forth with information about fraudulent claims when this information is not otherwise publicly available. On the other hand, Congress does not want self-serving opportunists, who do not possess their own

insider information, to get in on the action and try to collect on parasitic claims when the allegations have already been publicly disclosed and the opportunists have nothing new to add. The "based upon" language in § 3730(e)(4)(A) is the means through which Congress strikes the balance between these two competing policies. If we rewrite the statute to effectively include the "same or substantially the same" language, we are eliminating otherwise valid insider claims that Congress currently allows to go forth. Perhaps, this class of claims should be eliminated, but that is a policy choice reserved for the Congress and we must respect its current decision. As the Relators' proposed third amended complaint does not appear to be based upon publicly disclosed information, the jurisdictional bar of § 3730(e)(4) does not apply and therefore we shall turn to the merits.

B. The Merits

The district court determined that the Relators' proposed third amended complaint did not meet the heightened pleading requirements of Rule 9(b), refused the Relators leave to file the amended complaint under Rule 15(a), and dismissed the case. "We review a denial of a motion for leave to amend a pleading under an abuse of discretion standard." *Gagan v. Am. Cablevision, Inc.*, 77 F.3d 951, 968 (7th Cir.1996) (citing *Moore v. Indiana*, 999 F.2d 1125, 1128 (7th Cir.1993)). Rule 15(a) states that "leave [to amend] shall be freely given when justice so requires." Fed.R.Civ.P. 15(a). "Although the rule reflects a liberal attitude towards the amendment of pleadings,

courts in their sound discretion may deny a proposed amendment if the moving party has unduly delayed in filing the motion, if the opposing party would suffer undue prejudice or if the pleading is futile." *Campania Mgmt. Co., Inc. v. Rooks, Pitts & Poust,* 290 F.3d 843, 848-49 (7th Cir.2002) (citing *Foman v. Davis,* 371 U.S. 178, 181-82, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962); *Bethany Pharm. Co. v. QVC, Inc.,* 241 F.3d 854, 861 (7th Cir.2001)). Amending a complaint would be futile if the proposed amended complaint fails to satisfy the requirements of the federal rules. *General Elec. Capital Corp. v. Lease Resolution Corp.,* 128 F.3d 1074, 1085 (7th Cir.1997). Despite the fact that the deficiencies could be cured through an appropriate pleading, a district court properly exercises its discretion in dismissing the case when the plaintiff continually fails to provide a valid pleading in compliance with the federal rules. *See Emery v. Am. Gen. Fin., Inc.,* 134 F.3d 1321, 1322-23 (7th Cir.1998) ("[T]he plaintiff has had three chances over the course of three years to state a claim and the district judge was not required to give her another chance.").

We review a dismissal for failure to comply with Rule 9(b) *de novo* and take all factual allegations in the complaint as true and make all reasonable inferences in the plaintiffs' favor. *Borsellino v. Goldman Sachs Group, Inc.,* 477 F.3d 502, 507 (7th Cir.2007) (citing *General Elec. Capital Corp.,* 128 F.3d at 1078; *Goren v. New Vision Int'l, Inc.,* 156 F.3d 721, 725-26 (7th Cir.1998)). "The [False Claims Act] is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b)." *United States ex rel. Gross*

v. AIDS Research Alliance-Chicago, 415 F.3d 601, 604 (7th Cir.2005) (citing *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir.2003)).

Rule 9(b) requires that "[i]n all averments of fraud . . . , the circumstances constituting fraud . . . shall be stated with particularity." Fed R. Civ. P. 9(b). "A principal purpose for requiring that fraud be pleaded with particularity is, by establishing this rather slight obstacle to loose charges of fraud, to protect individuals and businesses from privileged libel (privileged because it is contained in a pleading)." *Kennedy v. Venrock Assoc.*, 348 F.3d 584, 594 (7th Cir.2003) (citations omitted). The heightened pleading standard requires "the plaintiff to do more than the usual investigation before filing his complaint. Greater precomplaint investigation is warranted in fraud cases because public charges of fraud can do great harm to the reputation of a business firm or other enterprise (or individual)." *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir.1999) (citations omitted). "A complaint alleging fraud must provide 'the who, what, when, where and how.'" *Borsellino,* 477 F.3d at 507 (quoting *Gross,* 415 F.3d at 605; *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.1990)).

The False Claims Act imposes civil liability for a series of actions under § 3729(a). The two applicable sections for this case are §§ 3729(a)(1) and (a)(2). Under § 3729(a)(1), civil liability is imposed on any person who knowingly presents a false claim to the government for payment or approval. 31 U.S.C. § 3729(a)(1). To establish

a claim under this section, "a relator must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States ex rel. Walker v. R & F Prop. of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir.2005). Section 3729(a)(2) prohibits a person from knowingly making a false record or statement to get a false or fraudulent claim paid or approved by the government. 31 U.S.C. § 3729(a)(2). The three elements of a § 3729(a)(2) claim are: "(1) the defendant made a statement in order to receive money from the government, (2) the statement was false, and (3) the defendant knew it was false." *United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 856 (7th Cir.2006) (quoting *Gross*, 415 F.3d at 604).

The first alleged fraud involves billing for returned prescriptions. The Relators allege that a percentage of federal employees who received prescription drugs under their respective health plans returned the drugs unused to Caremark. Despite receiving the returned merchandise, the Relators allege that Caremark continued to bill the government for the cost of these medications or failed to provide a refund if the government had already paid before the return was made by the federal employee. The Relators also argue they have identified specific transactions with particularity as they identified individual prescriptions that were returned to Caremark and corresponding invoices in which Caremark continued to bill for this returned merchandise.

Appendix A

We recently addressed a similar type of alleged scheme in *Crews*. *Crews* involved a false claims suit brought by a pharmacist who worked at a pharmacy providing pharmaceutical services to nursing homes in the local area. 460 F.3d at 854. Approximately 60% of the nursing home patients served by the pharmacy were on Illinois Medicaid—which is jointly funded by the State of Illinois and the Social Security Administration—thus implicating the False Claims Act. *Id.* Prescriptions would often be returned unused to the pharmacy, for example when a nursing home patient died. *Id.* at 855. The returned medicine would then be recycled and reused by the pharmacy. *Id.* However, the pharmacy, which we characterized as "shoddy," *id.* at 854, did not properly restock the returned medicine but instead commingled the returned drugs in garbage cans. *Id.* at 855. In turn, the labels for the reissued medicine did not properly reflect the lot number or expiration date. *Id.* This type of mislabeling is a violation of federal law and the pharmacy was eventually shut down by the government. *Id.*

After the pharmacy was shut down, Crews decided to do a little math. She saw that 60% of the pharmacy's patients were on Medicaid and that 10 to 20% of the dispensed medications were returned, recycled and reissued by the pharmacy. *Id.* at 856. Consequently, Crews concluded that 6% to 12% of the recycled medications would have been redistributed to Medicaid patients, resulting in double billing and therefore false claims. *Id.* However, we rejected this argument because Crews had failed to provide two vouchers representing two separate charges for the same pill. *Id.* at 857.

Appendix A

The Relators present arguments as to Caremark's billing for returned prescriptions fail for the same reason. The Relators allege that they have particularized evidence demonstrating that Caremark billed for prescriptions despite the fact that they were returned. However, like the situation in *Crews*, the Relators only have one-half of the evidence they need to survive under Rule 9(b). The Relators do not present any evidence *at an individualized transaction level* to demonstrate that Caremark failed to provide an appropriate refund or replacement product for a returned prescription. The Relators see the returned prescription but they do not know whether Caremark replaced the returned prescription with another prescription without charge. The Relators also see an invoice seeking payment for a prescription they allege has been returned and should not be paid, but they do not have any evidence to demonstrate that Caremark failed to reconcile this excess payment on a future invoice or through an otherwise proper accounting technique.

The core of the Relators' failure in this case is caused by their misunderstanding of what is required to bring a cause of action under §§ 3729(a)(1) and (a)(2). Both sections require a false claim or statement and knowledge that the claim or statement is false. *Crews*, 460 F.3d at 856; *Walker*, 433 F.3d at 1355. Remember what the Relators' employment positions were at Caremark, they worked at two of Caremark's distribution facilities. Thus, it makes sense that they would see drugs being returned and this could raise their suspicions. But what they lack is knowledge of Caremark's financial activities

and in particular how Caremark addressed these returns. The Relators err by assuming, without any support, that once a prescription was returned, Caremark automatically either kept the money or continued to bill without providing an appropriate credit to the government or replacement prescription to federal employees.

Furthermore, a person must *knowingly* present a false claim to the government for payment or *knowingly* make a statement in order to receive payment from the government. 31 U.S.C. §§ 3729(a)(1), (a)(2) (emphasis added). "The *mens rea* element, 'knowingly,' requires that the defendant have actual knowledge of (or deliberately ignore or act in reckless disregard of) the truth or falsity of the information. . . . Thus, 'innocent' mistakes or negligence are not actionable." *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544 (7th Cir.1999) (citing 31 U.S.C. § 3729(b); *Hindo v. Univ. of Health Sci./The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir.1995)). Although the proposed third amended complaint and its accompanying exhibits span several hundred pages, the Relators fail to provide any information addressing whether Caremark knowingly took any improper actions sufficient to implicate the False Claims Act.

It is also important to stop at this point of the discussion and note the scope of our review. We are reviewing the Relators' proposed third amended complaint to determine whether the Relators have met the requirements of the federal rules. As to this alleged

scheme, and as we shall see with all the alleged schemes, the Relators have failed to meet the Rule 9(b) pleading requirements. That is our only purpose here and we leave it to others, whether other relators, the government, consumers, the press, or Caremark itself, if any group so chooses, to determine whether there are problems with Caremark's business practices. We are simply holding today that the district court properly dismissed the case because the Relators, after being given several chances, could not fashion a complaint in compliance with the federal rules.

The Relators next argue that their proposed third amended complaint satisfies Rule 9(b) as to the allegations made about the "CCM Program." The CCM Program involved a cost saving procedure. Caremark and the participating private health plans reached an agreement under which Caremark would review submitted prescriptions and determine whether the prescribed drug could be appropriately replaced by a less expensive alternative. Caremark, however, could not unilaterally change the prescription but instead had to contact the prescribing doctor who had issued the original prescription. If the doctor agreed to take Caremark's cost saving suggestion, Caremark was allowed under the agreement to bill the health plans for a percentage of the savings. The Relators allege that Caremark did not properly contact the prescribing doctor before making the cost saving substitution. Thus, the Relators allege that Caremark submitted false claims when it submitted invoices for the cost savings on prescriptions that were altered despite not being previously approved by the prescribing physician.

This allegation also fails because the Relators do not provide any information to satisfy the knowledge requirement of the False Claims Act. There is no evidence in the proposed third amended complaint that Caremark had actual knowledge of this issue or otherwise ignored or disregarded this situation. At best, the "scheme" as currently alleged by the Relators merely rises to a breach of contract dispute between the health plans, the government and Caremark. The Relators' position taken in relation to this scheme, and permeating throughout this entire case, is effectively that any allegedly inaccurate claim is by definition a false claim. This standard would transform every inaccurate claim into a false claim and consequently replace the Act's knowledge requirement with a strict liability standard.

Finally, the Relators alleged three other schemes. They argue that Caremark committed fraud when it refused to substitute a generic for the name brand drug "Prilosec." The Relators also allege a "Lost in Transit" scheme and a "Turnaround" scheme. The Relators take issue with the district court, arguing that the district court dismissed these claims with a minimal amount of explanation. Yet, the Relators' brief before this court discusses each scheme over one page each for a total of three pages for all three schemes. The total citation to authority in the three pages of briefing consists of one case from the Eastern District of Pennsylvania. "We repeatedly have made clear that perfunctory and undeveloped argument, and arguments that are not supported by pertinent authority, are waived." *United States v. Hook*, 471 F.3d 766, 775 (7th Cir.2006) (citations

omitted). As such the Relators' arguments on these three schemes are waived. Additionally, should we reach the merits, consistent with our previous discussion, the Relators have failed to provide any indication that Caremark knowingly engaging in a fraud.

In conclusion, the Relators' proposed third amended complaint does not meet the requirements of the federal rules. Therefore, the district court properly exercised its discretion in denying the Relators' motion to amend their pleading and in dismissing the case.

III. CONCLUSION

The judgment of the district court is AFFIRMED.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED NOVEMBER 30, 2006

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

Civil Action No.: 03 C 8714

UNITED STATES OF AMERICA *ex rel.* MICHAEL FOWLER, PEPPI FOWLER, VICTOR CORTES, and DANNY NEVAREZ, as relators under the FALSE CLAIMS ACT,

Plaintiffs,

v.

CAREMARK RX, INC., a Delaware corporation, and CAREMARK, INC., a Delaware corporation,

Defendants.

MEMORANDUM OPINION AND ORDER

Michael Fowler, Peppi Fowler, Victor Cortes, and Danny Nevarez brought a *qui tam* action against their former employer, Caremark, Inc., and its parent, Caremark Rx, Inc. (collectively "Caremark"), alleging fraud involving the distribution of prescription drugs to federal health insurance plan members. Plaintiffs

initially filed a four-count amended complaint under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and state false claims statutes. The amended complaint was dismissed for failure to plead fraud with particularity and to comply with state *qui tam* procedures. *United States ex rel. Fowler v. Caremark Rx, Inc.*, No. 03 C 8714, 2006 WL 1519567, at *6 (N.D.Ill. May 30, 2006) ("*Fowler I*"). Plaintiffs filed a second amended complaint, dropping the state claims. Again, the court dismissed the complaint for failure to adequately plead fraud. *United States ex rel. Fowler v. Caremark Rx, Inc.*, No. Civ.A. 03C8714, 2006 WL 2425331, at *7 (N.D.Ill. Aug.21, 2006) ("*Fowler II*"). The court required plaintiffs to seek leave before filing a third amended complaint. Plaintiffs now move to do so under Fed.R.Civ.P. 15(a). Caremark objects. For the reasons set forth below, plaintiffs' motion is denied and the case is dismissed.

BACKGROUND

Plaintiffs filled this lawsuit in December 2003. Pursuant to 31 U.S.C. § 3730, the complaint remained under seal while the United States Attorney's Office conducted an investigation to determine whether it would intervene. The government declined intervention in January 2006. The court vacated the sealing order shortly thereafter.

While the case was under seal, plaintiffs filed an amended complaint. The amended complaint alleged that Caremark, a pharmaceutical services company with revenues of $8 billion, submitted millions of dollars in

false claims to the federal government in violation of federal and state false claims statutes. *See Fowler I*, 2006 WL 1519567, at *1. The alleged false claims arose from five government contracts obligating Caremark to provide prescription drugs to members of federal health insurance plans. *Id.* According to plaintiffs, the fraud was extensive. First, Caremark falsified the dates when prescription drug orders were received from thousands of plan members. *Id.* Caremark did this because it was inundated with orders and unable to meet contractual fulfillment deadlines. *Id.* By falsifying the date orders were received, Caremark gave itself more processing and delivery time and avoided non-performance penalties. *Id.* Second, Caremark routinely double-billed the government for prescription drugs returned by plan members. *Id.* When drugs were returned, Caremark restocked and resold them but failed to credit the government for the returns. *Id.* Third, Caremark committed various other frauds, including falsifying prescription dates, fraudulently altering existing prescriptions, delaying and cancelling drug orders without notice, manipulating internal records, and refusing to make less-expensive generic drugs available to plan members. *Id.* at *2. According to plaintiffs, these acts were not isolated; Caremark implemented national policies and procedures to systematically defraud the government. *Id.* at *1.

Although the amended complaint consisted of 250 paragraphs and 49 pages, it was short on substance. Caremark moved to dismiss the complaint for failure to plead fraud with particularity. The court agreed, holding

that Caremark failed to "set forth facts identifying the 'who, what, when, where and how' requirements for pleading fraud." *Fowler I*, 2006 WL 1519567, at *3 (quoting *United States ex rel. Gross v. Aids Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir.2005). Plaintiffs' "brief sketch" of the alleged fraud did not meet Rule 9(b)'s heightened pleading standards. *Id.* The court granted Caremark's motion and dismissed the amended complaint without prejudice. *Id.* at *6.

Plaintiffs filed a second amended complaint in June 2006. The complaint made its predecessor look anemic by comparison. It consisted of 514 paragraphs covering 178 pages, with over a thousand pages of exhibits. *Fowler II*, 2006 WL 2425331, at *3. Plaintiffs dropped the state law claims, focusing instead on three alleged schemes violating the False Claims Act. First, Caremark fraudulently concealed its failure to meet turn-around times for filling drug orders. *Id.* at *2. Caremark accomplished this three ways: falsifying receipt dates of prescription orders, shipping aging orders to other Caremark facilities to be processed as newly-received, and seeking unnecessary confirmations from plan members to process orders as a way to restart the fulfillment clock. *Id.* Second, Caremark overcharged the government for "intervention services" designed to reduce waste in the insurance plans. *Id.* Caremark obtained authorization to change patients' prescriptions from persons other than the prescribing doctors, and then used these unauthorized "switches" to generate savings for the insurance plans and performance bonuses. *Id.* Third, Caremark restocked all returned

drugs after only a cursory inspection and resold them without regard to plan members' safety. *Id.* at *3. The government was never credited for the returns; instead, Caremark charged the government again when it resold the returned drugs. *Id.* In support of their claims, plaintiffs attached annual guarantee analyses, savings reports, and invoices identifying over 20,000 prescription orders allegedly filled with returned drugs. *Id.* at *2-3.

Once again, Caremark moved to dismiss based on Rule 9(b), and the second amended complaint was dismissed. The court found the latest complaint elaborated on plaintiffs' personal knowledge of the alleged schemes, added lists of culpable Caremark employees, and identified invoices containing purported false claims. *Fowler II*, 2006 WL 2425331, at *6. However, the complaint "d[id] not identify a single prescription through which Caremark perpetrated the alleged fraud. Nor d[id][it] tie a specific fraudulent transaction to an invoice submitted to the government." *Id.* The deficiencies pervaded the complaint. *Id.* at *2-3 (plaintiffs had not identified "a single order with [a] falsified turn-around time;" none of the savings reports identified "an instance of improper authorization;" and plaintiffs did not allege "a single instance when drugs were improperly restocked"). Accordingly, plaintiffs had not "satisf[ied] Rule 9(b)'s requirement to give Caremark notice of the alleged fraud." *Id.* at *6.

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The court also expressed dissatisfaction with the complaint's prolixity:

> When the first amended complaint was dismissed for failure to comply with Rule 9(b), plaintiffs were given an opportunity to cure pleading defects. In response, they submitted a 178-page complaint and over a thousand pages of exhibits. Laden with baffling acronyms, their sprawling pleadings raised questions whether they complied with Rule 8(a)'s requirement of a "short and plain" statement. And despite receiving clear instructions, they failed again to plead fraud with particularity. Plaintiffs' repeated failure to comply with Rule 9(b) instills little confidence that a blank check to amend the complaint would serve any purpose other than drawing another motion to dismiss on the same grounds.

Id. at *7 (internal citations and footnote omitted). Despite the admonition, the court determined plaintiffs' allegations were not factually frivolous. *Id.* Therefore, the second amended complaint was dismissed without prejudice, and plaintiffs were required to file a motion for leave to file a third amended complaint. *Id.* The court warned that the motion for leave would be granted only if the proposed complaint complied with Rules 8(a) and 9(b). *Id.* On November 16, 2006, plaintiffs filed their motion for leave to amend, attaching a "streamlined" third amended complaint.

Appendix B

DISCUSSION

I. Legal Standards

A. Motion for Leave to Amend

Leave to amend a complaint "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). However, "a district court may deny leave to amend on the grounds of undue delay, bad faith, dilatory motive, prejudice, or futility." *Guise v. BMW Mortgage, LLC,* 377 F.3d 795, 801 (7th Cir.2004). Amending a complaint is futile if the proposed complaint fails to state a claim upon which relief could be granted. *General Elec. Capital Corp. v. Lease Resolution Corp.,* 128 F.3d 1074, 1085 (7th Cir.1997) ("[t]his standard is the same standard of legal sufficiency that applies under Rule 12(b)(6)"). A court need not grant leave to amend where a plaintiff has repeatedly failed to cure the same deficiencies. *Id.* This is especially true when a court provides "detailed analyses of the deficiencies of the prior complaints and explicit guidance for curing those deficiencies." *Airborne Beepers & Video, Inc. v. Southwestern Bell Mobile Sys., LLC,* No. 02 C 9134, 2006 WL 951877, at *2 (N.D.Ill. Apr.11, 2006) (Grady, J.).

B. False Claims Act and Rule 9(b)

Leave to file a third amended complaint turns on whether the proposed complaint states a claim under the False Claims Act. The pertinent provisions of the act impose liability on any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid by the Government; [or] (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(1), (2), and (7). The False Claim Act is an anti-fraud statute; therefore, it is subject to the heightened pleading standards of Fed.R.Civ.P. 9(b). *Gross*, 415 F.3d at 604. Under Rule 9(b), fraud must be alleged with particularity. Fraud claims must identify: (1) the person who made the alleged misrepresentation; (2) the time, place, and content of the misrepresentation; and (3) the method by which the misrepresentation was communicated. *General Elec. Capital*, 128 F.3d at 1078 (plaintiffs must plead the "who, what, when, where, and how" of the alleged fraud). In the context of the False Claims Act, plaintiffs must link specific allegations of deceit to claims for government payment. *Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir.2003).

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II. Insufficiency of the Third Amended Complaint

Plaintiffs proposed complaint alleges Caremark violated the False Claims Act by committing the following schemes: (a) improperly reselling returned drugs; (b) making unauthorized changes to prescriptions; (c) fraudulently altering turn-around times; (d) fraudulently reporting "CCR" savings; (e) refusing to provide generic drugs; and (f) misrepresenting prescriptions as "lost-in-transit." Caremark asserts the complaint fails to plead fraud with particularity because there are insufficient links between the alleged schemes and the claims submitted to the government. Caremark requests plaintiffs' motion for leave to amend be denied and the case be dismissed with prejudice.

Before turning to whether the alleged schemes are pled with particularity, the court is compelled to address plaintiffs' contention that it "streamlined" the third amended complaint. Mot. at ¶ 3. The present version contains 234 paragraphs covering 119 pages. It references 174 exhibits, comparable in mass to the 1000-plus pages of exhibits attached to the second amended complaint. While there are 59 fewer pages and 280 fewer paragraphs (demonstrating the bloatedness of the second amended complaint), plaintiffs add entirely new fraud schemes and recharacterize others. Many paragraphs contain run-on sentences with so many clauses they are confusing. *See e.g.*, Mot. at Ex. 1, ¶¶ 35, 150, 173. The third amended complaint is not a "streamlined version" of its predecessor. Plaintiffs continue to ignore Rule 8(a)'s requirement that pleadings

be "short and plain." Fed. R. Civ. P. 8(a); *Garst*, 328 F.3d at 378 (upholding dismissal of 155-page complaint with 99 exhibits because "judges and adverse parties need not try to fish a gold coin from a bucket of mud"). However, the court need not address Rule 8(a) in light of the discussion below.

A. Improperly Reselling Returned Drugs

The first scheme alleged in the third amended complaint is that Caremark restocked and resold returned prescription drugs.[1] Prescriptions were returned to Caremark for a variety of reasons. 3rd Am. Compl. at ¶ 23. Pursuant to Caremark's "national practices and procedures," the returns were restocked and resold to plan members. *Id.* at ¶ 24. Plaintiffs contend this violated Caremark's contracts with the government and was illegal under state law. *Id.* at ¶¶ 24, 33, 213. According to plaintiffs, Caremark submitted false claims by billing the government for prescriptions it knew were returned. *Id.* at ¶¶ 28, 57, 213. Caremark committed a further fraud by failing to credit the government for the returns. *Id.* at ¶¶ 29, 57, 213. Plaintiffs offer ten examples to support its allegations. *Id.* at ¶¶ 44-54. The examples follow the same pattern: a "Return Goods Memo" shows the dates a specific prescription was sent to a plan member, returned to Caremark, and restocked; excerpts of claim data show a federal insurance plan is billed for the restocked drug shortly after the return; and that

1. Plaintiffs' factual allegations are taken as true; all reasonable inferences are drawn in their favor. *See DeWalt v. Carter*, 224 F.3d 607, 612 (7th Cir.2000).

bill is included in a larger invoice sent to the government for payment. *See e.g., id.* at ¶ 44, Exs. 20-22. Based on these examples, plaintiffs contend Caremark made false claims for "every known returned drug." *Id.* at ¶ 43, Exs. 18, 19 (identifying over 20,000 prescriptions).

The Seventh Circuit recently addressed the sufficiency of an alleged restock/resale scheme under the False Claims Act. In *United States ex rel. Crews v. NCS Healthcare,* the plaintiff alleged prescription drugs were returned to the defendant's pharmacy, dumped in large bins, and then reused to fill future prescriptions. 460 F.3d 853, 855 (7th Cir.2006). According to the plaintiff, the defendant submitted false claims by double-billing the government for the recycled medications and failing to credit the government for the returns. *Id.* The complaint was deficient under Rule 9(b) because the plaintiff had not identified the alleged double-billed claims submitted for the drugs' initial purchase *and* resale:

> Crews needs to point to at least two vouchers to meet her burden: one voucher in which the [government] is billed for certain pills, and then a second voucher in which the [government] is billed again for at least one of the same pills. Without more, the [v]oucher standing alone proves nothing.

Id. at 857; *see also Quinn v. Omnicare, Inc.*, 382 F.3d 432, 440 (3d Cir.2004). The burden was on the plaintiff to "show the link between two vouchers that represent two separate charges for the same pill." *Id.* The failure-

to-credit allegations suffered the same fate because "Crews fail[ed] to point to a specific voucher, one which billed for drugs that were later returned, with no credit given." *Id.* at 857-58. The fraud failed for the additional reason that the plaintiff had not identified a federal regulation prohibiting the sale of returned drugs. *Id.* at 858. *Crews* makes clear that to allege a False Claims Act violation, a plaintiff must link specific allegations of deceit to claims for government payment. *Id.* at 857-58; *see also Gross*, 415 F.3d at 605; *Garst*, 328 F.3d at 378..

Plaintiffs' restock/resale allegations must be viewed in the context of *Crews*. Plaintiffs allege two distinct frauds as part of the scheme, *i.e.*, billing for returned drugs and failing to credit for returns. Both frauds are supported by examples that detail only the return and resale of prescriptions. *See e.g.*, 3rd Am. Compl. at Exs. 24-26 (the "Return Goods Memos," claim data, and invoices all relate to the resale of returned prescriptions). There are no specific allegations and no examples of claims regarding the initial purchase of the drugs. Plaintiffs are required to specifically allege a claim relating to the initial purchase, a second claim relating to the resale, and allegations of deceit linking the two. *See Crews*, 460 F.3d at 857.

This requirement applies to both alleged frauds. Submitting a claim to the government for the resale of returned prescription drugs is not fraud unless a claim was *already* submitted for the same drugs. *Id.* Submitting a claim that omits credits for returns is not fraud unless the government *already* paid for the

returns. *Id.* at 858. In other words, the claims alleged to be false in both frauds are only false based on prior claims submitted to the government. Plaintiffs' allegations attempt to characterize the frauds so only one claim is required to allege a violation. 3rd Am. Compl. at ¶¶ 28, 33, 213 (alleging single claim is false because Caremark knew drugs returned when made; alleging omitting credits in filed claim makes single claim false). But the substance of the allegations make clear that the frauds depend on an initial *and* subsequent claim. Therefore, plaintiffs must specifically allege "two separate charges for the same [drugs]" and "the link between [the] two." *Crews,* 460 F.3d at 857. While plaintiffs' examples are more detailed than the summary exhibits attached to the previous complaint, they still fall short of providing the necessary allegations under Rule 9(b). *Id.; see also Garst,* 328 F.3d at 378 (although relator had "come closer to specific allegations of deceit," the complaint was dismissed because he "fail[ed] to link them to any claim for payment").

Plaintiffs' allegations are deficient for the additional reason that they do not specifically identify which regulation or contractual provision Caremark violated. There is an initial question whether plaintiffs could ever allege a violation because the contracts are silent on whether Caremark is allowed to bill for returned drugs, 3rd Am. Compl. at Exs. 1, 2, 4-7, 9, 11, 13, and there is no regulatory requirement to reverse a claim once a drug is returned. *See Crews,* 460 F.3d at 858 (agreeing with analysis in *Quinn* that holds "there is no regulatory requirement of the reversal of a claim once a medication

has been returned"); *Quinn*, 382 F.3d at 438. Even assuming the existence of an obligation by Caremark, plaintiffs have not particularly alleged the basis of the obligation. The complaint generally alleges it is illegal under state law to bill for restocked prescriptions, 3rd Am. Compl. at ¶¶ 24, 26, and failing to credit returns violated the contracts, *id.* at ¶ 213. But Rule 9(b) is not satisfied by generalized allegations. *See Gross*, 415 F.3d at 605 (general reference to the "regulatory framework" was insufficient "to clarify the causal connection between false certifications and government payouts"); *United States ex rel. Raymer v. Univ. of Chicago Hosps.*, No. 03 C 806, 2006 WL 516577, at *8 (N.D.Ill. Feb.28, 2006) (Deryeghiayan, J.) ("without knowing *which* regulations are at issue, we cannot determine whether [the] alleged violations of unidentified regulations . . . affected NICU infants amounted to fraudulent misrepresentations"). Without particularized allegations, plaintiffs cannot properly plead a fraudulent restock/resale scheme.

B. Prescription Drug Changes

Plaintiffs next allege Caremark submitted false claims by misrepresenting that it obtained proper authorization to change plan members' prescriptions. The alleged scheme centers around Caremark's "intervention" programs, which had the purpose of generating savings for the government by reducing inefficiencies in the insurance plans. 3rd Am. Compl. at ¶¶ 61, 65. The programs are supposed to operate as follows: Caremark analyzes a plan member's prescriptions and identifies possible savings; the

prescriber is contacted and gives approval to change the prescriptions; the government saves money over the life of the prescriptions; and Caremark is paid for generating savings. *Id.* at ¶¶ 61-68. According to plaintiffs, Caremark made drug changes without prescriber approval, relying instead on authorization from nurses and receptionists. *Id.* at ¶ 73. Plaintiffs contend Caremark "billed and collected millions of dollars" from the government by claiming it properly obtained savings. *Id.* at ¶ 74. Plaintiffs provide approximately 20 examples they contend establish a "pattern and practice" of fraud. *Id.* at ¶¶ 80-148, 150. The examples include quarterly savings reports that allegedly incorporate unauthorized prescription changes. *See e.g., id.* at ¶¶ 88-90, Ex. 67. Plaintiffs also provide facsimile correspondence allegedly showing that Caremark made changes even though prescribers objected. *See e.g., id.* at ¶ 119, Ex. 95.

Neither plaintiffs' allegations nor the attached examples meet the pleading requirements of Rule 9(b). The majority of allegations contain boilerplate descriptions of how prescription changes were made without prescriber approval. Plaintiffs repeatedly allege that "further investigation, including, *inter alia,* telephonic contact with [the plan member]; the obtaining of a Release from [the member] for her prescriber's medical records; and contact with the prescriber's office, has revealed that refill elimination was made without prescriber approval." *See e.g., id.* at ¶¶ 80, 96. Plaintiffs do not identify who at Caremark called the prescriber's office, who at the office approved the change, or whether

that person was authorized to do so. Plaintiffs' entire scheme is premised on unauthorized prescription changes being incorporated into false claims. But plaintiffs have not alleged the changes or the false claims with enough detail to put Caremark on notice of the fraud. *See Garst,* 328 F.3d at 378 (essential to link allegations of deceit with claims); *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.1990). Plaintiffs' previous complaints failed to provide this detail; the third amended complaint does not rectify the deficiency. *See Fowler II,* 2006 WL 2425331, *2.

The allegations supported by faxed authorization forms are similarly deficient. First, each allegation partially relies on the same boilerplate language described above. 3rd Am. Compl. at ¶¶ 115, 125, 142, 145. Second, only three of the four faxes provided indicate no prescription change should be made, and they only relate to one insurance plan. *Id.* at ¶¶ 114, 124, 141, Exs. 91, 95, 101. In other words, the alleged fraud, which plaintiffs contend afflicts every insurance plan, is supported by three examples pertaining to a single plan. Rule 9(b) does not require "a detailed description of each and every false claim when the fraud took place over many years;" however, plaintiffs must give Caremark adequate notice of the alleged fraud. *See In re Cardiac Devices Qui Tam Litig.,* 221 F.R.D. 318, 334 (D.Conn.2004) (citing *United States ex rel. Pogue v. Diabetic Treatment Ctrs.,* 238 F.Supp.2d 258, 268 (D.C.Cir.2004). Three faxes over a four year period that

relate to one federal plan do not provide sufficient notice.[2]

Even assuming plaintiffs provided more examples, they have not alleged a false claim with the requisite particularity. Plaintiffs allege certain year-end savings reports are false because of Caremark's "pattern or practice" of misrepresenting that it obtained authorized prescription changes. 3rd Am. Compl. at ¶ 150. But plaintiffs do not specifically allege what the reported savings were, how those savings were inaccurate, whether Caremark would have met savings targets without the unauthorized changes, or the government's financial loss from the fraud. Instead, plaintiffs generally allege the false savings reports "were used by Caremark to avoid paying monetary obligations ('penalties') that it otherwise owed to those plans." *Id.* Plaintiffs fail to provide any specifics regarding the savings targets or the "monetary obligations." Their conclusory allegations fail to plead fraud with particularity. *See Veal v. First American Sav. Bank,* 914 F.2d 909, 913 (7th Cir.1990)

2. The paucity of examples is highlighted by the extensive discovery plaintiffs conducted in this and related cases, including reviewing over 100,000 Caremark documents received from the United States Attorney's Office, *Fowler II,* 2006 WL 2425331, at *3, analyzing over 20,000 invoices, 3rd Am. Compl. at Exs. 18, 19, manually reviewing more than 13 million prescriptions, Mot. at ¶ 3, and contacting prescribers' offices to obtain plan members' medical records, *see e.g.,* 3rd Am. Compl. at ¶ 145. Plaintiffs' argument that they are unable to provide more detail because Caremark controls certain information lacks merit. *See Fowler I,* 2006 WL 1519567, at *4 (exceptions to Rule 9(b) relaxing pleadings standards do not apply).

("[c]onclusory allegations do not satisfy the requirements of Rule 9(b) and subject the pleader to dismissal").

C. Turn-Around Times

Plaintiffs' proposed complaint alleges Caremark committed a scheme to defraud the government by misrepresenting the time in which it "turned around" prescription orders. Caremark was obligated under the contracts to meet certain turn-round time goals or it would be penalized, 3rd Am. Compl. at ¶ 151. Plaintiffs contend Caremark shipped orders between its own facilities, altered the dates prescription orders were received, and cancelled "old" orders to positively impact average turn-around times. *Id.* at ¶¶ 154, 155. According to plaintiffs, Caremark directed its employees to commit fraud "on a national basis" to ensure it met contractual guarantees and did not incur penalties. *Id.* at ¶ 153. Plaintiffs rely on approximately ten individual and summary examples in support of its allegations. *Id.* at ¶¶ 159-71, Exs. 120-136, 151, 174. Each example identifies the date the prescription order was received, the date it was sent to another facility, and the subsequent "false" received date. *See e.g., id.* at ¶ 168, Ex. 129.

After reviewing the exhibits, it is clear the third amended complaint does not plead the turn-around time scheme with particularity. The most glaring deficiency is plaintiffs' failure to identify any false invoices submitted to the government. Plaintiffs have failed to cure this defect from the prior complaint. *See Fowler II,*

2006 WL 2425331, at *7. Instead, plaintiffs attach "Guarantee Analysis" reports and allege they demonstrate a "pattern of fraud." 3rd Am. Compl. at ¶ 170. But only two reports are tied to substantive allegations, and they relate to only one insurance plan. *Id.* at ¶¶ 164, 170, Exs. 124, 134. Two examples relating to one plan cannot support allegations of company-wide fraud. The additional examples are referred to only summarily, making it impossible to determine what specifically is false about the reports and why. *Id.* at ¶¶ 170, 171, Exs. 135, 136, 151-60. Without particularized information regarding the false claims, *i.e.*, when they were made, by whom, and what false information they contain, plaintiffs cannot establish the necessary link between the fraudulent scheme and the false claims. *See Crews*, 460 F.3d at 857; *Gross*, 415 F.3d at 605.

The allegations also fail because plaintiffs provide no specifics regarding how Caremark's alleged fraud impacted average turn-around times. Fraudulent turn-around times are at the heart of the fraud scheme. Yet Caremark is left to speculate what the target averages were, which prescription orders negatively affected those averages, and how much the averages were inflated by Caremark's fraud, *i.e.*, the extent of the alleged fraud. In addition, the target averages differ depending on the type of action required by Caremark, but the complaint does not separately address the targets or the reported savings attributed to each action. 3rd Am. Compl. at Exs. 1, 2, 4-6, 9. Further, Caremark's argument is well taken that an extraordinary number of prescriptions exceeding the turn-around time averages would be necessary to

materially alter those averages. Objections at 7 (pointing out that plaintiffs assert there are 13 million prescriptions at issue). But plaintiffs provide only a limited number of substantive examples relating to one insurance plan with no explanation of how the averages are affected. 3rd Am. Compl. at ¶¶ 164, 170, Exs. 124, 134. Plaintiffs simply do not carry their burden to link the fraudulent turn-around time scheme to specific false claims. *See Crews*, 460 F.3d at 857 (plaintiff's burden, especially when it is statistically possible that fraud had no effect on allegedly false claim).

D. Reported "CCR" Savings, Generic Prilosec, and Drug Orders "Lost-in-Transit"

Plaintiffs allege three additional schemes in which Caremark defrauded the government: (1) Caremark misrepresented the amount of savings caused by its "CCR" cost-saving services, 3rd Am. Compl. at ¶¶ 172-91; (2) it refused to provide plan members with a generic version of Prilosee, *id.* at ¶ 192-98; and (3) it improperly billed the government for refills when members' prescription drugs were lost or stolen in the mail, *id.* at ¶ 199-210.

All three alleged schemes fail for the same reason: the conclusory allegations do not link the alleged frauds with false claims. Plaintiffs rely on phrases such as "each one of the monthly invoices," *id.* at ¶ 181, "each and every one of those CCR Quarterly Reports," *id.* at ¶ 183, "each and every occasion," *id.* at ¶ 194, "[e]ach and every time," *id.* at 203, and "regular practices and procedures,"

id. at ¶ 207, to support its claims. Plaintiffs also rely on hypothetical allegations. *Id.* at ¶¶ 177, 201 (alleging Caremark "might" do something and stating "if Caremark sent an order for drug 'X' to Federal Plan Member 'ZZ'). Further, the examples provided are summary in nature or heavily excerpted. *See e.g.*, Ex. 148 (one document attached as a group exhibit listing only nine prescriptions without explanation). There are few, if any, substantive allegations identifying contractual provisions or state laws Caremark purportedly violated. There are even fewer identifying false invoices or bills submitted to the government. In fact, in 38 paragraphs alleging three separate schemes, there is not one concrete allegation describing the who, what, when, where, why, and how of the alleged frauds. *See General Elec. Capital,* 128 F.3d at 1078. Plaintiffs fail to tie particularized allegations of wrongdoing to specific false claims. *See Crews,* 460 F.3d at 858. This is exactly what caused the dismissal of plaintiffs' second amended complaint, and it warrants denial of plaintiffs' motion for leave to amend.

CONCLUSION

The original complaint was filed in December 2003. Since then, plaintiffs have attempted three more times to plead a False Claims Act violation with particularity. While the amended complaints have grown in size (from 70 paragraphs to as large as 514 paragraphs with over 1000 pages of exhibits) and complexity, each have failed to plead a fraud scheme with sufficient detail to satisfy Rule 9(b). Over the past year, the court granted two of

Caremark's motions to dismiss, issuing detailed opinions alerting plaintiffs to the deficiencies in their allegations. *See Fowler I*, 2006 WL 1519567, at *2-4; *Fowler II*, 2006 WL 2425331, at *2-3, 6-7. Despite the court's instructions, plaintiffs' latest proposed complaint fails to cure the highlighted defects. Each new complaint requires Caremark and the court to invest considerable time and resources culling through the claims, drafting motions to dismiss, and responding to objections. At some point, the court must "throw up [its] hands" and dismiss the case. *See Garst*, 328 F.3d at 376. Now is that point. Plaintiffs have had ample opportunity, time, and direction by the court over the past three years to draft a valid cause of action. They have simply failed to do so. Future attempts to state a fraud claim adequately would be futile. Therefore, plaintiffs' motion for leave file a third amended complaint is denied, and the case is dismissed with prejudice. *See Garst*, 328 F.3d at 376; *General Elec. Capital*, 128 F.3d at 1085 (the court has discretion to dismiss a claim with prejudice after denying a plaintiffs' Rule 15(a) motion).

ENTER:
s/ Suzanne B. Conlon
Suzanne B. Conlon
United States District Judge

November 30, 2006

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT DENYING PETITION FOR REHEARING DATED SEPTEMBER 7, 2007

UNITED STATES COURT OF APPEALS
for the Seventh Circuit
Chicago, Illinois 60604

September 7, 2007

Before

Hon. KENNETH F. RIPPLE, *Circuit Judge*

Hon. MICHAEL S. KANNE, *Circuit Judge*

Hon. TERENCE T. EVANS, *Circuit Judge*

No. 06-4419

UNITED STATES *ex rel.* MICHAEL FOWLER, PEPPI FOWLER, VICTOR CORTES, and DANNY NEVAREZ,

Plaintiffs-Appellants,

v.

CAREMARK RX, L.L.C., and CAREMARK INC.,

Defendants-Appellees.

Appendix C

ORDER

On consideration of the petition for rehearing with suggestion for rehearing en banc, no judge in active service has requested a vote on the petition for rehearing en banc* and the judges of the panel have voted to deny rehearing. It is, therefore, ORDERED that rehearing with suggestion for rehearing en banc are DENIED.

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* Judge Flaum did not participate in the consideration of this petition for rehearing.